PERINATAL OUTCOMES FOR WOMEN DIAGNOSED WITH GESTATIONAL DIABETES MELLITUS WHO PARTICIPATED IN AN INTERDISCIPLINARY GESTATIONAL DIABETES PROGRAM

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ABSTRACT

The purpose of this descriptive study was to describe the case management process and report the perinatal outcomes of women in an interdisciplinary gestational diabetes mellitus (GDM) program. This study examined the structure of the team which implemented the program, related the process employed by team members to achieve euglycemia, and analyzed the perinatal outcomes of the participants. This study found there was insufficient documentation of interactions between study participants and team members. This lack of documentation hindered a clear description of the case management process. Outcomes were similar to outcomes reported by other GDM perinatal programs. Important observations included reduction in frequency of blood glucose evaluations by women the week prior to delivery and limited evaluation of blood glucoses during the intrapartum period. To determine the quality and effectiveness of perinatal case management programs further examination of the structure, process, and outcomes of case management must be conducted.

CHAPTER 1

INTRODUCTION

Diagnosis and treatment of women with gestational diabetes mellitus (GDM) continues to be an important health care issue. The perinatal risk is less for women with GDM versus Type I diabetes mellitus but there are no differences in fetal risks such as neonatal hypoglycemia, birth trauma, fetal macrosomia, and overall infant morbidity (Blank, Grave, & Metzger, 1995; Moore, 1994). GDM occurs ten times more frequently than Type I or Type II diabetes mellitus in pregnancy (Roversi et al., 1980). Therefore, the impact of the potential diagnosis and treatment of women with GDM can greatly exceed the impact of treatment of pregnant women with pregestational diabetes. Although an estimated 6 million cases of all diabetes mellitus are undiagnosed in the United States (U.S.) the event of pregnancy allows GDM to be identified through laboratory screening (American Diabetes Association [ADA], 1995c). Case management is one tool used by health care workers which enables women with GDM to achieve healthy perinatal outcomes and provides this at-risk aggregate potential avenues to delay or avoid the risk of Type II diabetes mellitus development (Rossi & Dornhorst, 1996). This researcher examined short term maternal outcomes associated with diabetic symptom management in an effort to identify a process of care that minimized neonatal morbidity associated with gestational diabetes mellitus.

Gestational Diabetes Mellitus

Gestational Diabetes Mellitus (GDM) is the classification of carbohydrate intolerance of variable severity (Metzger & the Organizing Committee, 1991) first recognized during pregnancy (ADA, 1995a). Three to five percent of all pregnancies are estimated to develop reversible carbohydrate intolerance secondary to the metabolic stress of pregnancy. GDM is sometimes referred to as gestational carbohydrate intolerance since the long-term effects postdate the index pregnancy (National Diabetes Data Group, [NDDG], 1979; O'Sullivan, 1991). Some evidence exists correlating the severity of glucose elevations during pregnancy with the risk of subsequent Type II diabetes development (Blank et al., 1995; Damm, 1996). When carbohydrate intolerance persists after delivery pregestational diabetes is diagnosed.

Women with a history of GDM may prospectively avoid GDM in future pregnancies by weight loss (ADA, 1995b; Damm, 1996; Hollingsworth, 1992; Rossi & Dornhorst, 1996). There also exists evidence that through proper management of GDM development of Type II diabetes may be delayed or avoided altogether (Hare, 1989; Moore, 1994). Avoidance of GDM in future pregnancies and delay or avoidance of Type II diabetes mellitus (primary and secondary disease prevention) is important secondary to costs associated with all types of diabetes mellitus and the seriousness of the potential long-term effects of the disease (Blank et al., 1995; Edelstein, 1996; Elixhauser, 1992). Education regarding primary and secondary prevention of Type II diabetes following pregnancies complicated by GDM could result in lifestyle changes reducing the development of diabetes and cardiovascular disease (Rossi & Dornhorst, 1996). The

Centers for Disease (CDC) estimated in excess of $92 billion dollars spent in 1992 on health care for patients with all types of diabetes (CDC, 1993).

Prevention of illness as well as symptom management for all illnesses is supported by cost-conscious managed care systems and case management strategies (Erkel, 1993; Holt, 1990; Institute of Medicine[IOM], 1996; Migchelbrink, Anderson, Schultz, & St. Charles, 1993; Mullahy, 1995). New models of health service delivery attempt to decrease overall costs of health care (Bard, Jimenez, & Tornack, 1994; Cohen & Cesta, 1993; Petryshen & Petryshen, 1992). Providers of care therefore seek ways to provide more cost effective care through reorganization and restructuring efforts (Blancett & Flarey, 1995; McCloskey et al., 1994).

Health care reform and fewer health care dollars focus the attention of consumers on issues of cost and quality of care received (Reinhart, Anderson, & Clay, 1995; Rhodes, 1994). Providing quality, research-based health care is critical during this time of change (Viau et al., 1995).

Quality may be assessed by judging the process of care and how that care results in outcomes that are of value (Donabedian, 1982; Lang & Marek, 1992). One approach to quality assessment is Donabedian's proposed paradigm of structure-process-outcome (1966; 1982; 1988b). Donabedian's paradigm was the conceptual framework for this study.

The impact of GDM as a disease state is discussed in relation to the incidence of the disease, and the maternal and neonatal complications. Available treatment modalities are reviewed as well as the need to conduct further GDM research.

Incidence of GDM

Three to five percent of pregnant women develop GDM (Blank et al., 1995). Women who are diagnosed with GDM are at increased risk for developing Type II diabetes mellitus (O'Sullivan et al., 1974). Children born to these women are also at risk for physical complications from birth (respiratory complications for example) to adulthood (metabolic weight control problems) (Hawthorn, Snodgrass, & Tungridge, 1994; Hollingsworth, 1992; Pettitt et al.,1991; Tallarigo et al.,1986). Pettitt (1996) called diabetes in pregnancy, to include GDM and Type I and II diabetes mellitus, a "vicious cycle..." since the mother's diabetes during pregnancy may result not only in neonatal complications for these children, but they "...are much more likely to go on to be obese and to develop diabetes; they may already have diabetes by childbearing age" (Blank et al., 1995, p. 128).

Maternal Complications

Increased rates of operative deliveries and birth trauma have been associated with GDM (Bernstein & Catalano, 1994; Coustan & Imarah, 1984). Women with a history of GDM have a greater risk of GDM reoccurring in succeeding pregnancies or manifesting itself as Type II diabetes mellitus or noninsulin-dependent diabetes 10-15 years after the diagnosis (NDDG, 1979; O'Sullivan, 1991). Glycemic control during pregnancy can directly affect the potential for subsequent diabetes development for this population (Blank et al., 1995).

Neonatal Complications

The original intent of treating GDM was to prevent excess perinatal mortality and

congenital anomalies. GDM differs from diabetes mellitus. GDM does not cause congenital anomalies because glucose metabolism is normal in the first trimester when organogenesis occurs (Hare, 1989). Although infant mortality is rare today, infant morbidities associated with GDM occur frequently. These morbidities include macrosomia with potential birth injuries and traumatic delivery (shoulder dystocia), hyperbilirubinemia, hypoglycemia, hypocalcemia and poor fetal lung maturation (American College of Obstetrics and Gynecology [ACOG], 1994; ADA, 1995a; Blank et al., 1995).

Treatment Modalities

Most women diagnosed with GDM can control their blood glucose levels through a combination of diet and exercise (ADA, 1995d). Other women require the addition of exogenous insulin to maintain euglycemia. Through education the risks and morbidities associated with GDM can be communicated. Lifestyle changes during pregnancy can delay or prevent long-term risks of developing diabetes mellitus and improve neonatal outcomes (Hare, 1989; Moore, 1994). Use of surveillance methods can encourage women to maintain their glycemic status within a prespecified range (Moore, 1994). Adherence to established standards of care by health care providers may reassure women with GDM about the quality of care received.

Research Needs

To provide quality care, nursing and other health care professionals search for research based interventions upon which clinical practice should be based (Dufault, 1995; Heater, Becker, & Olson, 1988). The Committee to Study the Prevention of Low

Birthweight, Division of Health Promotion and Disease Prevention, Institute of Medicine, (1985) acknowledged the need for research that goes beyond the question of whether prenatal care improves pregnancy outcomes. Instead this committee recommended the investigation of well-defined aggregates of pregnant women and their response to specific services that may be effective in preventing numerous poor perinatal outcomes.

Case Management

The need for health care agencies to limit losses and deliver health care that is more cost-effective has resulted in a growing interest in case management (Rawsky, 1996). Case management is a process comprised of patient-focused strategies to coordinate care while balancing quality outcomes, and costs (Case Management Society of America [CMSA], 1995; Petryshen & Petryshen, 1992). Therefore continuity of patient care across the health care continuum has been identified as an important aspect of case management services (Kurtin, 1995). One goal of case management is to provide effective interventions on an out-patient basis in order to prevent or delay expensive acute episodes of care (Tackenberg & Rausch, 1995).

Often, case management is provided by a health care team of social workers, physicians and nurses (Marschke & Nolan, 1993). Use of interdisciplinary teams in various settings has resulted in reduced costs of health care and improved outcomes for clients (Boucher & Classen, 1991; O'Toole, 1992). This model of care has been documented in the management of diabetes (Edelstein, 1996) and the treatment of diabetes in pregnancy (Hollingsworth, 1992). Interdisciplinary team conferences provide

a time for sharing of concerns regarding the client, review of the progress made by the client, and consolidation of a plan of care for each client.

Diabetes in Pregnancy Clinic

Pregnant women with diabetes mellitus are often seen in a high-risk obstetric and gynecologic (OB/GYN) clinic. The OB/GYN clinic used as the site for this research designates one morning a week, identified as the Diabetes in Pregnancy Clinic (DPC), to the care of these women. The purpose of this clinic is to provide comprehensive diabetes education and management using an interdisciplinary team approach.

Program participants attend the clinic at least weekly where they are instructed on the disease process, signs and symptoms of hypoglycemia, self-monitoring of capillary blood glucose, self-administration of insulin, and diet therapy. Exercise is not included as a type of therapy in this program. During clinic appointments values recorded in blood glucose logs are compared to values recorded by individual reflectance blood glucose meters. Glycemic control is evaluated for compliance and therapy is changed by the providers as needed. Dietary needs are assessed to facilitate the participant's glycemic control. Psychosocial needs as well as routine prenatal testing recommendations are evaluated and referrals are made.

Statement of the Problem

The problem under investigation in this study was the effect of diabetic symptom management via an interdisciplinary case management team on short term maternal outcomes of women with GDM. Neonatal outcomes associated with this method of diabetic symptom management for women with GDM were also studied.

Purpose of the Study

The purpose of this study was to describe an interdisciplinary gestational diabetes program which employed the process of case management and report the perinatal outcomes of the program participants. This research was accomplished by describing the process employed by team members to achieve euglycemia in the program participants, and analyzing the outcomes of women with gestational diabetes and their newborns who participate in the program.

Research Questions

Research questions in this study concerned the process and outcomes of an interdisciplinary gestational diabetes program, DPC. The questions were:

Related to Process:

1. How many DPC visits did program participants attend?
2. What was the period of contact for the participants attending the DPC?
3. With what frequency did each member of the interdisciplinary team interact with participants over the duration of the pregnancy?
4. What percentage of participants were referred to resources not provided by the interdisciplinary team?
5. What percentage of time were the participants compliant in seeking the recommended referrals?
6. How many participants were treated with diet alone?
7. How many participants were treated with diet and insulin therapy?

Related to Outcome:

8. What was the maternal weight gain during pregnancy for participants?
9. What was the number of blood glucose values obtained on a daily basis by participants during the four week period prior to delivery?
10. What were the last seven fasting blood glucose values obtained for the participants prior to delivery?
11. What were the last seven days' postprandial blood glucose values obtained for the participants prior to delivery?
12. What were the glycosylated hemoglobin ($HgbA_{1c}$) values for the program participants at program enrollment and at program completion?
13. What were the birth weights and birth percentiles (using gestational age) of the offspring born to program participants?
14. What were the incidences of newborn complications such as hypoglycemia, hypocalcemia, and shoulder dystocia occurring in program participants?

Definition of terms

1. Interdisciplinary diabetes program is a prenatal care program for women with diabetes provided by a team of physicians, nurses, a dietitian, and a nurse case manager. The interdisciplinary diabetes program provides comprehensive diabetes education and management and is named the Diabetes in Pregnancy Clinic (DPC).

2. Gestational diabetes program participants are women with at least two abnormal OGGT values whose prenatal care is performed by the interdisciplinary team

and who deliver at one designated facility.

3. Period of contact is the length of gestation from program enrollment until delivery.

4. Interactions with a member of the interdisciplinary team include documented discussions or teaching accomplished during DPC appointments, documented telephone calls, and documentation of care either on an outpatient or inpatient basis with a team member.

5. Outcome is any measurable result that occurred during gestation which might contribute to a greater understanding of maternal or neonatal health.

6. Maternal weight gain during pregnancy is the value recorded in the labor and delivery record.

7. Blood glucose is the level of sugar found in the blood stream. Glucose is formed during digestion by the action of enzymes on carbohydrates and absorbed into the blood stream in the intestines. University Medical Center's (UMC) standard for normal blood glucose is 70-110 mg/dL for adults and 50-130 mg/dL for newborns (UMC, 1996).

8. Fasting blood glucose value is the first value measured in the morning prior to ingestion of food and administration of insulin. The desired fasting blood glucose value for DPC participants is 60-100mg/dL (K. B. Lesser, personal communication, 5 November, 1996).

9. Postprandial blood glucose values are obtained two hours after a meal. The desired postprandial blood glucose value for DPC participants is 80-120mg/dL (K. B. Lesser, personal communication, 5 November, 1996).

10. Glycosylated hemoglobin ($HgbA_{1c}$) is a particular fraction of a glycosylated hemoglobin molecule. Glycosylation occurs during the 120-day life span of the red blood cell (RBC). Under normal conditions the mean circulating glucose during the RBC's life span correlates closely with $HgbA_{1c}$ levels (Moore, 1994). The $HgbA_{1c}$ values considered to be normal are between 4.4 % - 6.4% (UMC, 1996).

11. Neonatal birthweight is the weight recorded in the newborn record.

12. Birth weight percentile is the classification of newborns according to birth weight norms by gestational age and by gender (Arbuckle, Wilkins, & Sherman, 1993; Varner, 1994). Newborns in the 10^{th} percentile or below are classified as small for gestational age (SGA) while newborns in the 90^{th} percentile or above are classified as large for gestational age (LGA). Infants whose fetal growth is considered normal fall between 11^{th} and 89^{th} percentiles and are classified as appropriate for gestational age (AGA).

13. Hypoglycemia is blood glucose plasma level less than 35 mg/dL for term infants or a chemical test strip value less than 40 mg/dL (UMC, 1996).

14. Hypocalcemia is blood calcium plasma level < 8.0 mg/dL (< 2.00mmol/L) for term infants (Demarini, Mimouni, Tsang, Khourny, & Hertzberg, 1994).

15. Shoulder dystocia occurs during a difficult vaginal delivery when the infant's shoulders and torso become lodged in the birth canal, requiring assistance through manual rotation, superpubic pressure, or neonatal fracture to complete delivery (Thomas, 1997).

Significance of the Study

This study relates how an interdisciplinary team utilized the process of case management in diabetic symptom management of women with GDM. Documentation regarding the case management process is important in order to evaluate a more scientifically rigorous study which would allow a cause and effect relationship to be established (Polit & Hungler, 1995).

Summary

Aggressive management of gestational diabetes mellitus (GDM) is important in order to reduce avoidable maternal and neonatal morbidities. Case management is a process of seeks service coordination through a multidisciplinary approach, is one method to optimize glycemic control for women with GDM. Case management interventions which are based on research are not well documented in the literature. Alternative health care delivery models, such as case management, must be thoroughly evaluated to determine their impact on process and outcome.

Quality assessment is part of model evaluation. Donabedian's (1992) paradigm of structure-process-outcome is one method used to assess the presence of quality health care. Research using this paradigm is important to establish relationships between the abstract level of Donabedian's constructs and the operational level of specific concepts (Rawls-Bryce, 1996).

CHAPTER 2

CONCEPTUAL FRAMEWORK/ LITERATURE REVIEW

In this chapter, literature on quality assessment supporting the use of the structure, process, and outcome paradigm to evaluate the quality of health care is reviewed first. This is followed by a statement of the conceptual framework. Then completing this chapter a review of the literature concerning GDM, its treatment regimens, and various maternal and neonatal morbidities are noted. The process of case management and the use of interdisciplinary teams are incorporated to include examples in the management of GDM.

Quality Assessment

Quality may be assessed by judging the process of care and how that care results in outcomes that are of value (Donabedian, 1982; Lang & Marek, 1992). According to Donabedian (1990), a definition of quality health care is required prior to assessment of that care. Whether viewing health care from the vantage of the practitioner, client or society affects this definition of quality. He further explains the need to evaluate the quality of health beginning with health care practitioners who are central to the levels at which quality can be assessed. Practitioners can be evaluated based upon two elements; technical and interpersonal elements. Technical performance includes strategies of care as well as implementation of those strategies, and is judged in relation to a "gold standard" or care that is recognized or theorized to result in the highest attainment of health (Donabedian, 1988a). Despite negative outcomes, technical quality may be

judged to be high if the actions of the health care practitioner conformed to this "gold standard". Interpersonal aspects of quality are composed of the relationship between the practitioner and the client which may or may not be therapeutic.

Once quality health care is defined, specific criteria indicating delivery of quality health care must be established (Hamric,1989). An approach to assessment of quality was first proposed and further refined by Donabedian (1966; 1986). This structure-process-outcome paradigm is used as the conceptual framework for this study.

Various tools have been employed by health care agencies to facilitate continuous quality improvement efforts (Rawsky, 1996). Kurtin (1995) used the acronym "SUCCESS" to communicate clinical tools which she describes as crucial in creating an effective health care system and promote mutual accountability between the consumer and the health care provider. "System evaluation; unrelenting communication; continuous improvement; case management; empowerment; standards-based clinical practice; and satisfaction of the patient, family and care provider are some of the tools available to develop systems that effectively manage health and illness" (Kurtin, 1995, p. 100).

Criteria Formation

In order to evaluate outcomes, specific criteria indicating delivery of quality health care must first be established (Hamric, 1989). Implementation of the ADA Standards of Pregnancy Care is receiving increased attention secondary to the trend towards case management and avoidance of adverse outcomes (Elixhauser et al., 1992). One of the primary goals of the ADA standards is strict blood glucose control in order to

avoid macrosomia and the associated birth trauma, neonatal hypoglycemia and respiratory distress in the newborn. Recommendations to facilitate glycemic control include dietary instruction, blood glucose self-monitoring, exercise, patient education, laboratory evaluations ($HgbA_{1c}$), and frequent provider interaction.

Nursing interventions and related patient outcomes of 84 experimental studies (N = 4146) were analyzed by Heater and associates (1988). These studies were conducted by nurses and nurses provided the interventions. All patient outcomes resulted from nursing interventions which were based upon specific criteria and were measurable. Outcomes were identified as psychosocial, behavioral, physiological or knowledge based. A change in the client's ability to relate either intrapersonally or interpersonally was considered to be a psychosocial outcome. Behavioral outcomes related to how the client controlled their actions while physiological outcomes, such as pulse rate, were compared to changes from baseline data. The category of knowledge outcomes was in reference to the client's level of cognitive understanding. A significant difference (0.001) was noted in the effect size of random assigned subjects (0.69) versus nonrandom assigned subjects (.32). This meta-analysis indicated that patients treated with research-based nursing interventions realized 28 percent better outcomes (defined separately for each study) than 72 percent of patients who received standard nursing care.

Formation of criteria can be made according to structure, process, and outcome as described by Donabedian (1988a, 1988b). Caregiver characteristics and administrative and institutional factors are considered structural criteria (Hamric, 1989). Process is

related to the role which can be one of education, research, direct care, or consultation and to what actions are performed for the patient. Outcome is the results of a specified intervention (Lang & Marek, 1992).

Related to Process

Adherence to ADA Standards is a measure of process of care indicator. The ANA Nursing Care Report Card for Acute Care includes "assessment and implementation of patient care requirements" as a process of care indicator (1995, p. 59).

In a study of process, costs, and outcomes the Corner (an adolescent community-based prenatal care program) was compared to the OB Clinic (a traditional prenatal care program caring for teenagers). There was a total of 360 adolescents in the sample. The following criteria describing the process of care enabled researchers to compare the two programs. The process of receiving care included the mean number of prenatal visits (12.79 for the Corner versus 9.79 for the OB Clinic), the mean number of nonscheduled outpatient visits (0.63 for the Corner versus 1.06 for the OB Clinic), the mean number of ultrasound evaluations (0.67 for the Corner versus 1.32 for the OB Clinic), the mean number of nonstress tests (0.30 for the Corner versus 0.72 for the OB Clinic), and the mean number of inpatient days during pregnancy (0.58 for the Corner versus 0.69 for the OB Clinic) (Kay et al, 1991). The two programs were found to be statistically different in the stated criteria except for the number of inpatient days during pregnancy. Clients attending the Corner program were seen more frequently but in less technology-intensive visits than the OB Clinic program which resulted in a 60 percent reduction in costs for the community program.

Related to Outcome

Nursing outcomes have been described and measured using multiple methods according to Lang and Marek (1992). Measures such as knowledge, physiological status, behavioral measures, symptom control, nursing diagnosis resolution, and utilization are found in the literature. One example is the evaluation of a diabetes education program conducted by Tilly, Belton and McLachlan (1995) in which health status was based on glycemic control ($HgbA_{1c}$) over a 6 months period.

Use of blood glucose levels and compliance with guidelines is documented as an outcome measure by Horn and Swain (1978). Another measure of outcome is utilization of services or use of resources (Lang & Marek, 1992). If referrals for services were made then high resources use could be viewed as a positive outcome.

Kay and associates (1991) also studied outcomes in their community versus traditional prenatal care program for adolescents discussed earlier. Criteria used to compare the outcomes of the two prenatal care programs consisted of birthweight, gestational age, percentage of infants requiring neonatal intensive care, as well as the percentage of clients with maternal complications. No statistically significant outcome differences were noted via multivariate analysis.

Conceptual Framework

Reliance on measures of process alone to perform quality assessment assumes a direct relationship between the process and the outcome (Brook et al., 1977). This assumption is questionable because quality is also related to reliability and validity of the

technique used to obtain data on process, the methods used to judge the quality of process of care, in addition to the relationship of process and outcome. Until a direct relationship is supported empirically process and outcome should be used in concert to assess the quality of care.

Donabedian's model (1966, 1982, 1988a, 1988b, 1992) of structure, process, and outcome as criteria and standards for quality assessment and monitoring is used as a conceptual framework to relate the concepts of case management via an interdisciplinary team and the resulting perinatal outcomes of a maternal cohort. Because the structure of the interdisciplinary team is already known, a description of the setting, health care system, as well as the professional and educational backgrounds of the team members will be presented in Chapter 3. This multidimensional assessment of quality organizes complex criteria that may include many intervening variables indicating the delivery of quality health care in a simplistic way and facilitates identification of failures in quality achievement (Figure 1). According to Hogston (1995) Donabedian's framework has been previously used in nursing as well as other health care settings as a way to establish standards of care. Specific standards related to various process and outcome indicators specific to this study have already been discussed.

Structure is concerned with the setting and or system in which health care is performed and the attributes of the health care providers. According to Donabedian structure may pertain to the physical or organizational properties of the setting and if health care is performed under suitable settings with the presence of appropriate supports

CONCEPTUAL FRAMEWORK

CONSTRUCT LEVEL	→ CONCEPT LEVEL	→ OPERATIONAL LEVEL
↓	↓	↓
PROCESS	**Case Management**	Frequency of Meetings Length of Contact Number of Interactions Percentage Referred Percentage Sought Referral Type of Referral
OUTCOME	**Perinatal Outcomes Maternal**	Average Weight Gain Average Number of Glucose Values over last 4 weeks prior to delivery Average Postprandial Blood Glucose Values 7 days prior to delivery Average Change in Glycosylated Hemoglobin Values
	Perinatal Outcomes Neonatal	Birthweight by Percentile (SGA, AGA, LGA) Incidence of Hypoglycemia, Hypocalcemia, Shoulder Dystocia

Figure 1. Conceptual Framework Based on Donabedian's Paradigm (1966)

quality health care will result (1992). Hamric (1989) in an effort to evaluate clinical nurse specialist (CNS) used Donabedian's model and included CNS qualifications, nurse-patent ratios, utilization of caregivers, and presence of support personnel as structural variables.

Process is concerned with how care is delivered or what happens during the care of the patient (Donabedian, 1992). The process of health care that corresponds to what is most acceptable to the patient and to society and what is thought to be most beneficial in improving health is defined as good or quality health care per Donabedian (1990). Hamric (1989) described six different types of process evaluations in her article. Strategies included were evaluation of CNS activities by other nurses, peer review, evaluation of CNS expertise by another health care professional or consumer of health care, self-evaluation or performance review through comparison with job description or using personal goals and objectives, and audit of nursing process improvements. These evaluations examine the caregiver's activities in relation to effectiveness. In Hogston's (1995) study of nurses, a multidisciplinary process in which teamwork was evident indicated to those nurses the presence of quality care. This article pointed out the importance of collaborative care in the achievement of quality care.

Outcome is defined by Donabedian (1990) as clinical changes in the patient's health as a result of the care provided or the end result of a specific process of care. This definition may apply to outcomes associated with changes in knowledge, behavior, or attitude as well as health (Donabedian, 1992). Quality is not directly assessed by outcomes although inferences regarding quality in relation to structure and process may

be made. Hamric noted "the most thorough evaluation correlates process to outcome by examining relationships between caregiver practice and patient outcomes" as is accomplished in process-outcome evaluation (1989, p. 94). In the absence of valid criteria that are scientifically based expert agreement can supplement or replace scientific evidence (Donabedian, 1992).

Lamb indicates a need for nurse case management research, including "the structure, process, and outcomes of case management" (1995, p. 126). She points out the concentration of research into the area of outcomes with little systematic inquiry into the clinical process behind nursing case management.

Gestational Diabetes Mellitus (GDM)

Routine prenatal testing includes monitoring of urine, blood pressure and weight. Additional prenatal screening in the U.S. involves screening for factors that place the fetus at increased risk for developmental or physical abnormalities during pregnancy (Freeman & Poland, 1992). These factors include maternal medical conditions, demographic, obstetric and concurrent maternal factors.

Historical Perspective

Treatment of women with diabetes in pregnancy began in 1824 when Dr. Bennewitz recorded the first case of diabetes that occurred during pregnancy and resolved after delivery (Hadden, 1996). Women having insulin-dependent diabetes mellitus (IDDM) rarely survived two years after diagnosis of their disease much less risked pregnancy that often resulted in the loss of the pregnancy and risked the life of the

mother (Firth, 1996). With the discovery of insulin in 1921, an association was made between improved blood glucose control and perinatal outcomes.

GDM was recognized as a disease in 1964 when O'Sullivan and Mahan performed a 100 gram 3-hour oral glucose tolerance test (OGTT) on 752 pregnant women and followed all women with at least two values above two standard deviations beyond the mean to see if hyperglycemic women were predisposed to develop diabetes down the road. They determined that the metabolic stress of pregnancy revealed a woman's "pre-diabetic status." This finding agrees with observations that overweight women are more likely to have hyperglycemia in pregnancy and to develop diabetes later in life.

The original intent of treating GDM was to prevent excess perinatal mortality and congenital anomalies. GDM differs from diabetes mellitus in that GDM cannot cause congenital anomalies because glucose metabolism is normal in the first trimester when organogenesis occurs (Hare, 1989). O'Sullivan, Gellis, Dandrov, and Tenney (1966) prospectively evaluated 615 women shown to have abnormal glucose tolerance in pregnancy. These women were randomly assigned to either treatment with diet and insulin (positive treatment, $\underline{n} = 307$) or treatment as a routine obstetrical patient with no special diabetic management (positive control, $\underline{n} = 308$). A group of pregnant women with normal glucose-tolerance tests from the same clinic were also used as a control group (negative control, $\underline{n} = 328$). The number of babies weighing 9 pounds or greater were higher for the positive controls (13.1 %) than for the negative controls (3.7 %) or the positive treated controls (4.3 %). Viable losses were not significantly different between positive treated (4.3 %) or positive controls (4.9 %). Statistical significance was

noted when the positive group's number of viable losses were compared to the negative control's number of viable losses (1.9 %, $p < .01$) or the positive treated controls were compared to the negative controls ($p < .05$).

They found a significant increase in perinatal deaths in the GDM population. This was further demonstrated in 1973 when O'Sullivan, Charles, Mahan, and Dandrow performed a prospective study of 187 women with GDM compared with 259 randomly selected negative control patients. Perinatal mortality rate for the women with GDM was 6.4 % compared to 1.5 % for the control group ($p < 0.05$). The effect of maternal age on the perinatal mortality rate was significantly higher for women with GDM who were 25 years or older (9 %) compared to the control group in the same age (1.1 %). There was no difference in the perinatal mortality rate for women who were less than 25 years of age.

According to a recently released report from the Centers for Disease Control (CDC), the overall infant mortality rate in the U.S. for 1993 was 8.4 deaths per 1,000 live births, a new low infant death rate (Gardner & Hudson, 1996). Forecasts for 1994 using provisional data indicate a further drop to a rate of 7.9. These rates are still alarming when compared to other countries: currently the U.S. ranks 19th in infant mortality rates (U. S. Public Health Service, 1991). Infants born to mothers with GDM contribute to these death rates under the category of certain conditions of the perinatal period (Gardner & Hudson, 1996).

Pathophysiology

Maternal plasma glucose must be within specific parameters referred to as euglycemia (Hare, 1989). By the 10^{th} week of gestation normal fasting blood glucose levels are between 70 and 80 mg/dl (Palmer, 1994). Euglycemia is important since fetal glucose values are 80 percent of the maternal levels. Fetal demands create a metabolic shift during pregnancy (Hollingsworth, 1985). The mother feeds intermittently with periods of fasting while the infant requires continuous energy supplies from embryogenesis through delivery.

Insulin, an anabolic hormone, is essential for the proper metabolism of carbohydrate, fat and protein and the maintenance of euglycemia (Palmer, 1994). As the maternal levels of estrogen and progesterone rise during the first few weeks of pregnancy pancreatic β-cell hyperplasia and insulin secretion are stimulated (Moore, 1994). A concurrent elevation in the tissue's ability to store glycogen occurs coupled with a rise in peripheral glucose utilization, a decrease in hepatic glucose production, and a reduction in fasting plasma levels of maternal glucose. An anabolic metabolic change is created secondary to the increased sex steroids and hyperinsulinemia. Consequently blood glucose levels are higher postprandially.

The placenta acts as an endocrine organ during pregnancy duplicating steroids, synthesizing peptides that are hypothalamic and pituitary-like in nature, stimulating the production of growth hormones and pregnancy-related proteins (Hollingsworth, 1992). This creates enhanced storage of fuel during the fed state and enhanced metabolism during the fasting state. Human placental lactogen hormones, or human chorionic

somatomammotropin (hCs), are antagonistic to insulin while stimulating metabolism of glucose and its conversion to fat. These hormone levels increase as the placental mass increases (Moore, 1994). Placental synthesis of peptide and steroid hormones reaches a peak during the second half of pregnancy allowing carbohydrate intolerance to be detected (Harris, 1988). Levels of hCs increase in the third trimester of pregnancy, facilitating free fatty acid metabolism as an energy source for the woman with GDM. As the placenta develops, fat stores are facilitated by progesterone as a source of energy reserve for the fetus and lactating mother. Another hormone that increases as the pregnancy progresses is cortisol which is active in metabolism of glucose and fats. An enzyme produced by the placenta, Insulinase, increases the breakdown of insulin. This enzyme also effects the adrenal glands increasing cortisol production which in turn accelerates formation of glycogen from fatty or amino acids, non-carbohydrate sources, straining the GDM mother's carbohydrate metabolism.

Two specific metabolic interactions distinguish gestational diabetes from other types of diabetes mellitus. Elevated glucose concentrations are not recognized by β-cells and insulin release is delayed (Hollingsworth, 1992). The diagnosis may be confused with previously undiagnosed, asymptomatic noninsulin-dependent diabetes mellitus (NIDDM).

Physical Measures

O'Sullivan and Mahan (1964) performed a 100-gram 3-hour oral glucose tolerance test (OGTT) on 752 pregnant women and followed all women with at least two values above two standard deviations beyond the mean to see if hyperglycemic women

were predisposed to develop diabetes down the road (Hare, 1989). The study population was 60 percent white and 40 percent black. Since diagnostic thresholds are set at two standard deviations beyond the mean, values for O'Sullivan and Mahan's population have arbitrarily been established as the norms for all women. This means that some women are being identified as diseased simply because of race. Studies show that when pregnant women undergo two OGTTs a week or so apart, test results disagree 22 percent to 24 percent of the time (Catalano et al., 1993; Harlass, Brady, & Read, 1991). An individual's blood sugar values after ingesting glucose (or food) vary widely depending on many factors. For this reason, the OGTT has been abandoned as a diagnostic test for true diabetes in favor of excessive fasting glucose values, which show much greater consistency, or postprandial values of 200 mg/dl or more, which are rare (ADA, 1995c). Moreover, pregnancy compounds problems with reproducibility. Because glucose levels rise linearly throughout pregnancy, a woman could "pass" a test in gestational week 24 and "fail" it in week 28. These same problems hold true for the glucose screening test that precedes the OGTT (Sacks, 1989; Watson, 1989).

No threshold has ever been demonstrated for onset or marked increase in fetal complications below levels diagnostic of true diabetes (Hare, 1989). O'Sullivan and Mahan (1964) chose their cutoffs for convenience in follow-up, but all studies since then have used their criteria or some modification thereof as a threshold for pathology in the current pregnancy. Numerous studies since have documented that birth weights and other outcomes fail to correlate with O'Sullivan's or anybody else's thresholds.

Maternal Considerations

The incidence of maternal morbidities is greater in pregnancies complicated by GDM than in pregnancies where glucose is normal. Magee, Walden, Benedetti, and Knoop (1993) reported higher incidences of maternal morbidities in women with GDM (n = 96) than in women without GDM as measured by a 50-gram glucose screen (n = 521 randomly selected) or those women with a positive screen but a negative 3-hour OGTT (n = 264). Statistically significant differences were noted for women in the GDM group with frequency of anemia (GDM = 16.7 %; Neg. OGTT = 9.4 %), cephalopelvic disproportion (GDM = 12.5 %; Neg. OGTT = 7.5 %), nonvertex presentation intrapartumly (GDM = 3.1 %; Neg. OGTT = 0.2 %), and cesarean section (C-section) deliveries (GDM = 30.2 %; Neg. OGTT = 21.5 %). Other studies report no differences between C-section rates for women with GDM (n = 159) versus women with a positive 50-gram screen and a negative OGTT (n = 151) (Lucas, Lowe, Bowe, & McIntire, 1993). One paper reported an increased rate of C-section in GDM (35.3 %) over the rate in a matched population with a normal OGTT (22 %) despite similar birth weights, but attributed this to an increased number of women in the GDM group who did not labor prior to surgery (Goldman, Kitzmiller, Abrams, Cowan, & Laros, 1991).

In Cousins' review of pregnancy complications over a 20 year period 1781 pregnancies were classified as GDM (1987). The overall C-section rate for this group was 20.4 percent; 12.4 percent primary and 9.8 percent repeat operations. C-section rates for all other diabetic pregnancies (3375) exceeded the GDM C-section frequency.

Coustan and Imarah (1984) demonstrated a statistically significant decrease in operative deliveries (primary C-section, midcavity vacuum extraction, and midforceps) and birth trauma (shoulder dystocia, cephalhematoma, soft tissue injury, and Erb's palsy) in GDM patients prophylacticly administered insulin versus patients treated with diet alone or untreated. These reductions in operative deliveries and birth traumas were also reflected in decreased rates of macrosomia supporting an earlier study which did not evaluate mode of delivery (O'Sullivan et al., 1974).

Risk associated with GDM postdate the index pregnancy. Early screening for GDM is indicated in women with a history of GDM in a previous pregnancy since the rate of reoccurrence of GDM is about 50 percent (Coustan, 1994). As stated previously the risk of Type II diabetes is significant for these women (O'Sullivan, 1991). Difficulty in study comparisons arise due to various diagnostic criteria used to diagnose GDM and variability in the time between the index pregnancy and the development of Type II diabetes.

Neonatal Considerations

GDM has been linked to perinatal morbidity secondary to complications at delivery (Blank et al., 1995). Dystocia, or difficult labor, refers to poor progress in labor as a result of multiple variables. Women with GDM are particularly prone to a complication known as shoulder dystocia; inability to deliver the infant's shoulders, which become lodged in the woman's pelvis. This may result in a traumatic delivery for both mother and baby, with a potential need to resuscitate the neonate after surgical intervention. Macrosomia, commonly defined as a birthweight greater than 4 kilograms,

has been associated with increased operative deliveries and birth trauma (Hod, Merlob, Friedman, Schoenfield, & Ovadia, 1991). High maternal glucose levels lead to increased insulin production in the fetus which converts the excess glucose into fat for storage. Infants of women with GDM deposit excess adipose tissue on the shoulders and trunk of the body, leading to asymmetrical development and increased weight (ACOG, 1994). Macrosomia occurs twice as frequently in infants born to women with GDM (Blank et al., 1995). Other side effects of increased insulin levels in neonates at delivery are linked to retardation of fetal lung maturation and neonatal hypoglycemia (ACOG, 1994). In a study of perinatal outcomes of 261 women with GDM (Gabbe, Mestman, Freeman, Anderson, & Lowensohn, 1977) 85 percent of the study sample had some neonatal morbidity. These morbidities included hyperbilirubinemia, hypoglycemia, hypocalcemia and traumatic delivery (ADA, 1995a).

All patients with GDM are at significant risk for fetal macrosomia and other neonatal morbidities, including hypoglycemia, hypocalcemia, polycythemia, and hyperbilirubinemia (Hawdon & Aynsley-Green, 1996). Magee and colleagues (1993) documented statistically significant higher rates of newborn resuscitation at delivery in women with GDM than in women who were either negative for GDM by a 50-gram glucose screen or those women with a positive screen but a negative 3-hour GTT. The offspring of mothers who experience both fasting (> 105 mg/dl) and postprandial (> 120 mg/dl) hyperglycemia are at greatest risk for intrauterine death or neonatal mortality, and such mothers must undergo careful antepartum fetal surveillance (Hollingsworth, 1992). Perinatal mortality for offspring of the patient with GDM who maintains normal fasting

and postprandial glucose levels is not increased above that observed in the general population under conditions of optimum obstetric care and restitution of fasting and postprandial plasma glucose to normal limits (Hawthorn et al., 1994). Hypoglycemia occurs if the mother's blood sugar levels have been consistently high, causing the fetus to have a high level of insulin in its circulation. Maternal insulin does not normally cross the placental barrier, resulting in the need for the fetus to increase insulin production to metabolize the glucose received (Moore, 1994). After delivery the baby continues to have a high insulin level with a normal glucose value, resulting in the newborn's blood sugar level becoming very low (Hollingsworth, 1992). This hypoglycemia is often resolved with breast or bottle feeding but could require treatment with glucose intravenously (Moore, 1994). Prospective controlled studies have not investigated the acute and long-term effects of hypoglycemia although the primary concern of neurological damage as evidenced by lower intelligence has been investigated (Hawdon & Aynsley-Green, 1996; Weiner, 1988). Babies with excess insulin become children who are at risk for obesity and adults who are at risk for Type II diabetes (Pettitt et al., 1991).

Although hypocalcemia is cited as a frequent biochemical development for the newborn of women with all types of diabetes the importance of this finding is yet to be documented (Hawdon & Aynsley-Green, 1996). Loss of maternal magnesium via the urinary system is thought to lower the magnesium level for both the woman and her fetus. This lower magnesium level in turn inhibits the neonatal parathyroid from its usual decrease and return to normal level during the newborn period resulting in

secondary hypoparathyroidism. A consequence of hypoparathyroidism is neonatal hypocalcemia (Demarini, Mimouni, Tsang, Khourny, & Hertzberg, 1994). Other causes proposed for the increased number of infants of diabetic mothers with hypocalcemia are preterm birth and asphyxia. Clinical signs of hypocalcemia are rare since this is often a self-limiting event.

Fetal macrosomia may occur in the GDM population three to six times more frequently than in the general population (Spellacy, Miller, Winegar, & Peterson, 1985). Metabolic disorders present in GDM promote macrosomia which the presence of maternal obesity appears to amplify. Prepregnancy body mass index (BMI) was supported to be a predictor of macrosomia more often than maternal weight gain for GDM and control groups in a retrospective study (Di Cianni et al., 1996). Delivery of infants greater than 4000 grams vaginally could induce birth trauma in GDM women, particularly those women who are obese.

The most common birth injury sustained by a neonate, clavicular fracture, results secondary to shoulder dystocia (Roberts et al., 1995). In a pair-matched control study of 215 cases of clavicular fracture (0.4 % of 65,091 vaginal deliveries) over a five year period the authors concluded this type of fracture was a complication of normal birth that is both unavoidable and unpredictable. The incidence of clavicular fracture in various prospective studies is approximately 3 percent of vaginal births and associated with an estimated gestational age greater than 40 weeks, shoulder dystocia, and macrosomia. A study by Keller, Lopez-Zeno, Dooley, and Socol (1991) noted half of the shoulder

dystocias in a study of 210 GDM deliveries occurred in infants weighing less than 4,000 grams.

Intervention Strategies

Diet Therapy

The best method of achieving euglycemia in GDM women and reducing morbidity in their infants is not known (Miller, 1994). Dietary management alone may be effective for 75 - 80% of the women with GDM (ADA, 1995d). All affected women should receive nutritional counseling, by a registered dietitian when possible, consistent with the recommendations for calorie distribution proposed by the ADA. Individualization of the diet should be ethnically acceptable and easily managed at home and away from home (Persily, 1996). Diet therapy should include the provision of adequate calories and nutrients to meet the needs of pregnancy, and should be consistent with the maternal blood glucose goals that have been established.

Diet therapy varies by body mass index (BMI) based upon prepregnancy body weight (ADA, 1995d). BMI is differentiated into lean if 19.8-26 kg/m2 and obese if BMI is greater than 29 kg/m2. Caloric restrictions of 1500-1800 kcal/day may be recommended for obese GDM women with an overall pregnancy weight gain goal of 15-20 pounds (25 kcal/kg ideal prepregnancy body weight). Diets that are high-carbohydrate, high-fiber, and low-fat with 2000-2400 kcal/day (36 kcal/kg ideal prepregnancy weight gain) are suggested for lean women with GDM. The pregnancy weight goal for lean women is 25-35 pounds. They are encouraged to eat three snacks per day and obese women are limited to daily bedtime snacks (Hollingsworth, 1992).

Other dietary guidelines are designed to avoid excess weight gain and encourage normoglycemia (ADA, 1995d). These include the ingestion of breakfasts that are less than 10 % carbohydrate (Peterson & Jovanovic-Peterson, 1991) and foods high in fiber. Convenience foods are more refined and result in blood glucoses that rise at a greater rate. They are also high in fat which increase the overall calories and lead to excessive weight gain. Sugars and concentrated sweets such as those found in some fruit juice could be avoided by emphasizing fresh foods and learning sources of hidden sugar. The recommended composition of carbohydrate, protein, and fat in the diet for women with GDM by percentage is 40, 20, and 40 percent respectively (Peterson & Jovanovic-Peterson, 1991).

Exercise Therapy

Exercise as a treatment modality for GDM has not gained the wide acceptance of diet and insulin therapy (ADA, 1995d; Avery & Rossi, 1994). Some sources state that the efficacy of exercise in GDM is poorly addressed in the literature (Hollingsworth, 1992). Support for exercise as a treatment modality for women with GDM who maintain an active lifestyle in the absence of medical or obstetrical contraindications and under medical supervision is supported by the Third International Workshop-Conference on Gestational Diabetes Mellitus (Metzger, & the Organizing Committee, 1991) as well as ACOG (1994).

Adding exercise to the general management scheme for individuals with diabetes in general has a physiologic rationale according to Artal (1996). Glucose uptake of a contracting skeletal muscle can increase by 35 percent. After exercise, glucose tolerance

is increased for variable periods, depending on both insulin availability and contractile activity. Muscles appear to help regulate the capacity for contraction-stimulated glucose transport (Rossi & Dornhorst, 1996). Even though the mechanism of glucose transport into cells that are sensitive to insulin during pregnancy has not been studied, exercise during this altered state of insulin sensitivity is logical.

Durak, Jovanovic-Peterson and Peterson (1990) demonstrated upper-body exercises did not produce uterine contractions although lower-body exercises might result in uterine contractions in healthy women in their third trimester of pregnancy. In their study on the safety of exercise, five types of equipment were examined to determine the type of exercise that did not result in low birth weight infants, fetal distress, maternal hypertension, or uterine contractions. Upper-arm ergometer was determined to be the most-acceptable and safest form of exercise for these women followed by recumbent bicycling. The other three forms of exercise resulted in uterine contractions.

Further research demonstrated 36 out of 40 cases where cardiovascular conditioning obviated the need for insulin therapy for women with GDM (Bung, Artal, Khodiguian, & Kjos, 1991; Jovanovic-Peterson, Durake, & Peterson, 1989). This type of exercises appears to avert insulin treatment by increasing insulin affinity for its receptor number and insulin binding to its receptor (Jovanovic-Peterson, & Peterson, 1991; Pederson, Beck-Nielson, & Heding, 1980). Jovanovic-Peterson and colleagues (1989) demonstrated positive changes in the fasting glucose levels and results of a 50-gram glucose challenge after only four weeks of exercise. In their study 19 women with GDM

were randomized into two groups. Group I was treated with diet only and group II was treated with diet and exercise. During the six-week study various glycemic parameters were measured to study the effects of diet versus diet and exercise on the subjects. Glycemic parameters were the same for both groups at the conclusion of week one. Fasting and postprandial blood glucose values as well as $HgbA_{1c}$ values were significantly different between groups at the end of the study. All three parameters for the diet and exercise group (group II) demonstrated greater glycemic control than for the diet only group (group I). For example the two groups' $HgbA_{1c}$ values were similar prior to the study ($p = 0.75$). At the conclusion of six weeks both groups had lower $HgbA_{1c}$ values and the difference between the groups was significant ($p < 0.001$) Exercise and diet combined resulted in the lowest $HgbA_{1c}$ values.

Insulin Therapy

If dietary management, or diet and exercise therapy combined does not consistently maintain the fasting plasma glucose < 105 mg/dL (< 5.8 mmol/L), and/or the 2-hour postprandial plasma glucose < 120 mg/dL (< 6.7 mmol/L) on two or more occasions within a one to two week interval, insulin therapy should be considered. Morbidity such as macrosomia might be reduced if lower fasting values such as those espoused by Hollingsworth (1992) are used; fasting plasma glucose(> 90mg/dL; 5.0mmol/L).

Secondary to the limited controlled studies regarding the use of oral hypoglycemic agents only human insulin is recommended during pregnancy in Western

society (Miller, 1994). Studies of tolbutamide, chlorpropamide (first-generation sulphonylureas), and phenformin (a biguanide no longer easily obtainable) were found to be teratogenic in embryo cultures. In Third World countries second-generation sulphonylureas (glyburide and glibenclamide) and/or metaforin (biguanide) have been used in moderate dosages (Firth, 1996).

A mixture of intermediate-acting (NPH) and short-acting (Regular) insulins in a two to one ratio administered 15 - 45 minutes before breakfast combats the most frequent type of hyperglycemia, postprandial. Fasting hyperglycemia is relieved by a single injection of NPH insulin at bedtime. Regular insulin may be added to NPH insulin and injected before the evening meal if both fasting glucose and evening postprandial level are elevated.

Normal-weight women with GDM have insufficient insulin reserves to maintain euglycemia postprandially. Treatment for this group includes a small dose of preprandial rapid-acting insulin. Obese women with GDM have impaired β-cell recognition of elevated glucose levels coupled often with insulin resistance as a consequence of their obesity (Hollingsworth, 1992). Reduced caloric intake coupled with small doses of rapid-acting insulin before each meal is generally effective. Some women will require a bedtime dose of intermediate-acting insulin to emulate a normal glucose profile for a complete 24-hour period. The impact of diet and insulin therapy on women with GDM who have normal or smaller-than-normal-sized babies for gestational age has not been well documented.

de Veciana and colleagues (1995) randomly assigned 66 women to postprandial and preprandial monitoring groups for insulin therapy to manage their GDM. They noted a decrease in the risk of neonatal hypoglycemia, macrosomia, and cesarean delivery when insulin therapy was adjusted based on the results of postprandial, rather than preprandial, blood glucose values along with improved glycemic control. Some centers have treated patients prophylacticly with insulin with demonstrable reductions in cesarean delivery rate and macrosomia (Hollingsworth, 1992).

Surveillance

Close surveillance of mother and fetus must be maintained in GDM. Fetal risk roughly parallels maternal glycemic control because fetal oxygenation is affected by hyperglycemia. Fetal hypoxia leads to an increased incidence of fetal distress in labor and neonatal asphyxia, which has been credited with the polycythemia and subsequent jaundice seen in infants of diabetics (Hare, 1989). Maternal surveillance should be directed toward monitoring for elevations of fasting or postprandial glucose in capillary blood or venous plasma and designed to detect any deterioration of glucose homeostasis as gestation proceeds. Self-monitoring of capillary blood glucose (SMBG) is a requirement for effective insulin therapy. Monitoring of maternal urinary glucose is not adequate or sufficient for effective insulin therapy. The SMBG technique will be used to determine blood glucose values unless otherwise stated. Reflectance blood glucose meters evaluate the blood sample by glucose oxidase reaction which increases the objectivity over visually read strips (ADA, 1995d; Carr, Slocum, Tefft, Haydon, & Carpenter; 1995).

Various recommendations regarding blood glucose surveillance in patients with GDM are found in the literature (Lorenz, 1996). The American Academy of Obstetrics and Gynecologists (ACOG, 1994) recommends a less aggressive approach by obtaining two weekly fasting and 2-hour postprandial blood glucose levels from the laboratory. The ADA (1995a) and most studies perform self-monitored blood glucose obtained four times daily. These include fasting and generally one to two hour postprandial levels (Miller, 1994). The use of patient glucose logs to verify data from glucometers is a key factor in monitoring glycemic control (Langer & Hod, 1996; Persily, 1996)

Control of diabetes by using glycosylated hemoglobin ($HgbA_{1c}$) as a retrospective index of average glycemia is well documented (Moore, 1994). It does not reflect hyper or hypoglycemia since it is an average of the previous 6 - 8 weeks glucose levels maintained by the body (Mayer & Freedman, 1983). $HgbA_1$ is different in that it measures $HgbA_{1a+b+c}$ and the range for normal is higher (5 - 7 %) than in $HgbA_{1c}$ (4 - 6 %) although both are referred to as "glycohemoglobin" (Shields, Gan, Murphy, Sahn, & Moore, 1993). When drawn in the first trimester this blood value can give a risk percentage for presence of abnormalities for gestational diabetes and facilitates the differential diagnosis of GDM (ADA, 1995a). Serial $HgbA_{1c}$ levels may be drawn every 6 - 8 weeks to assess overall diabetes control and verify the results of home glucose monitoring. This adjunct therapy for GDM remains controversial (Langer & Hod, 1996; Miller, 1994).

Fetal surveillance for women with GDM may differ between those who are controlled by diet therapy alone and those who are treated with insulin and diet therapy (Hollingsworth, 1992). The starting time, frequency, and techniques utilized to assess fetal well-being should depend on the cumulative degree of risk that the fetus is believed to bear (Landon & Gabbe,1996). Sonography is accomplished at various points beginning with a sonogram to confirm estimated date of confinement. Later scans may reveal altered patterns of growth (macrosomia, IUGR), observation for fetal abnormalities and anomalies, amniotic fluid levels, and doppler studies of the fetal umbilical artery (Lorenz, 1996). At 28 weeks fetal assessment by movement or "kick counts" (maternal assessment of fetal activity) may be started for both therapies. This is coupled with weekly non-stress tests at around 36 weeks' gestation and increased to twice a week testing after 40 weeks' gestation. By 40 weeks' gestation contraction stress tests and fetal biophysical profiles should be added if daily fetal movements have remained reassuring (Moore, 1994).

Timing and route of delivery is based on maternal factors such as vascular disease, glycemic control, condition of cervix, and previous OB history (Moore, 1994). Fetal considerations of estimated fetal weight, suspected distress, and presence of anomaly are taken into account. Amniocentesis for lung maturity and for amniotic fluid glucose levels may be obtained secondary to the increased incidence of respiratory distress in infants of mothers with GDM.

Case Management

The philosophy of case management, "to enhance quality of life while reducing the total healthcare costs" and to have a direct positive influence on "the social, ethical and financial health of the country and its population" (CMSA, 1995, p. 10), is congruent with the goals of perinatal healthcare. The specific functions of case managers, those of assessor, planner, facilitator, and advocate, lend themselves to the management of gravid women. Case management is one tool that can assist patients to identify and overcome barriers to health care (CMSA, 1995). McClanahan (1992) identified factors related to inadequate prenatal care as sociodemographic, system-related, and attitudinal. Mullahy (1995) posits that 3 to 5 percent of the patient population is high risk, critically injured, or inflicted with a chronic illness and therefore generate the greatest portion of healthcare costs. She contends early identification of this population is necessary to provide cost-effective, quality care while supporting cost containment strategies through the case management approach (Mullahy, 1995).

Population-based case management is a form of managed care based upon clinical epidemiology. Shamansky defines population-based managed care as "a collaborative effort to maximize health outcomes and lower costs for defined populations by assuring the delivery of effective services and eliminating ineffective ones" (1995, p. 211). She further describes diabetes as one type of subpopulation that is disease specific versus age or gender specific which could benefit from managed care. Population-based case management promotes the assessment and understanding of the health needs of a subpopulation. Internal policies and appropriate services to meet the needs of this

subpopulation can then be arranged. Wagner (1995) describes steps used to start a population-based managed program for individuals with Type I and Type II diabetes in Washington. Women with GDM constitute another type of subpopulation who are at increased risk for adverse perinatal outcomes and at increased risk for development of Type II diabetes over the general population following delivery (Damm, 1996).

Case management of at-risk populations is aimed at reduced length of hospital stays, decreased cases of avoidable patient readmissions, and increased satisfaction with health care delivery by patients, nurses, and physicians (Kurtin, Bohnenkamp, & Palmer, 1994; Lamb & Stempel, 1994). These goals are accomplished by monitoring chronic illnesses and encouraging utilization of needed services (Migchelbrink et al., 1993). Case management of patients with diabetes has been linked to ensuring quality care and reducing the cost associated with hospitalizations for diabetic patients (Korn, 1992). Interventions may begin at pregnancy for women with GDM and continue throughout the life of the mother and the child. Rossi and Dornhorst (1996) recommend preventive health care targeting women with a history of GDM. Potentially modifiable risk factors of future weight gain and obesity could be addressed through a low-fat diet, and regular exercise. Cardiovascular protective benefits of blood pressure control, cholesterol level monitoring, and smoking cessation could be shared through continuing education programs.

One aim of prenatal care is to avoid the high costs of treatment in the acute care setting. Prenatal care that consists of early and continuous risk assessment, health

education and promotion, and continuous health care for the women and her family as she is prepared for parenthood meets this goal (McClanahan, 1992).

Various models of case management exist today (Cohen & Cesta, 1993; Del Togno-Armanasco, Olivas, & Harter, 1989; Eckett, Vassallo, & Flett, 1996; Lamb & Stempel, 1994; Parsons & Murdaugh, 1994) to form care delivery models that are cost-effective and responsive to the clients' and staffs' needs (Goodwin, 1994; Olivas, Del Togno-Armanasco, Erickson, & Harter, 1989). No one model is perfect for every health care agency (Del Togno-Armanasco et al., 1989).

Interdisciplinary Model

Various professions perform the role of case manger. These include for example, social workers, occupational therapists, physicians, rehabilitation counselors as well as nurses (CMSA, 1995; Marschke & Nolan, 1993; Mullahy, 1995). Case mangers are hired with varying education levels in nursing (diploma graduate, associate degree, baccalaureate degree or above) or other professions and preparation in case management (formal continuing education course or degree granting education, or limited to no on the job training). Case managers are knowledgeable regarding various components of the health care system (Kurtin, 1995) and may be part of multiple interdisciplinary teams. As team members, case mangers can be vital to the integration of system components in order to provide solutions to particular patient problems.

Goodwin (1994) compared NCM activities in home health agencies, health maintenance organizations (HMOs) and case management companies in a descriptive study. Using the Competency Behaviors of Case Managers Inventory (CBCMI) she

measured the frequency of various case management activities based on elements of the nursing process: assessment; planning; intervention; and evaluation. A convenience sample of 88 NCMr resulted in 32 respondents to the CBCMI. Duplication of services between various NCM groups was identified as a possibility for this study, pointing to the redundancy likely in settings where multiple case managers represent the same client although the focus of the services may differ.

Various programs are being studied to determine their effectiveness in educating and following women with GDM (Hollingsworth, 1992). Multidisciplinary teams treating diabetes in pregnancy have proven successful towards patient education and improved perinatal outcomes (Boucher & Classen, 1994; Persily, Brown, & York, 1996). Boucher and Classen reported a decrease in the number of missed appointments by clients, improved blood glucose levels, and decreased hospitalizations for glycemic control. Persily and colleagues pointed out the importance of telephone follow-up of women with diabetes in pregnancy, with most of the help seeking calls associated with knowledge seeking (n = 133, 45.9 %). Diabetic educators are now employing computer based education programs (Lewis, 1996) coupled with highly technical glucometers to further patient education and improve documentation of glycemic status (Carr et al., 1995).

Interdisciplinary Team Management

Use of an interdisciplinary team to coordinate care for women with GDM based on case management was described by Boucher and Classen (1991). Use of a specialist from dietary and various nursing areas were included. In this study one nurse was a

certified diabetes educator (CDE) and another was an obstetrical clinical nurse specialist (CNS). Goals of care included greater continuity of care between health care departments, settings, and agencies throughout the length of the pregnancy, reduced health care costs and hospital admissions, and increased nursing satisfaction. Even though the perinatologist and obstetrical residents were not part of the team the goals of care were shared with them. Claims of reductions in missed appointments, reduction in hospitalization for diabetes related education, diet regulation and blood glucose control, as well as improved blood glucose values were made but not accompanied by supporting data. Program costs were minimal according to Boucher and Classen based upon achieved outcomes.

Use of multidisciplinary teams in the management of both inpatients and outpatients in New York were described by Edelstein (1993). The sample studied included 26 antepartum patients admitted for glycemic control ($\underline{N} = 160$). The number of patient consultations with a diabetes team member, length of hospital stay, readmission to the inpatient facility rates, and bedside blood glucose levels were measured. An average of 7.5 consultations per patient were noted. The average length of stay for study members with a primary diagnosis of diabetes was 4.14 days which increased to 10.7 days for a secondary diagnosis of diabetes. Two of the antepartum patients were readmitted within 30 days of inpatient discharge; the overall rate was 7.33 % for readmissions. Poor glycemic control was limited to 1.46 % of patients prior to discharge from the inpatient facility.

Factors Influencing Intervention Effectiveness

Patients should be motivated to participate in the management of their condition (Neiger & Kendrick, 1994). This could be accomplished through a program of comprehensive counseling and education provided to both the woman and her family. Women who weigh more than their ideal body weight should be counseled to lose weight before becoming pregnant due to the strong correlation between maternal weight and the rate of macrosomia. Other issues that should be addressed are the need for glycemic control, use of memory-based reflectance meters, proper dietary guidelines, inclusion of a moderate exercise program, the need for frequent clinic visits and telephonic contact, and early recognition of infections.

Adherence to methods of glucose control may be improved through education regarding the long-term consequences of untreated serum glucose elevations during pregnancy. According to O'Sullivan (1991) the incidence of GDM women developing Type II diabetes within 5 years of the index pregnancy is 50 % if insulin was employed as a method of glucose control. For women with GDM controlled by diet alone, there was a 60 % risk of diabetes within 10 - 15 years. Lifestyle changes such as weight reduction and ADA diet adherence can delay or entirely prevent the onset of diabetes.

Multiple factors are known to affect blood glucose levels (ADA, 1995d). Stress, various times of the day, the amount of carbohydrate digested, and exercise are influential towards euglycemia. Stress, whether psychological or physical, results in contrainsulin hormones which increase blood glucose levels. Pregnancy is one of the physical stresses. Others are various hormonal imbalances related to growth and

development, menstrual cycle, trauma, inflammation, or infection. High levels of cortisol and growth hormone in pregnancy increase the normal morning intolerance of glucose as well as the diurnal changes in the contrainsulin hormones. Blood glucose levels are directly affected by the amount of carbohydrates digested (Peterson, & Jovanovic-Peterson, 1991). This can lead to hyperglycemia in the morning if the percentage of carbohydrates consumed is not limited during breakfast when the body can least tolerate carbohydrates.

Standards of Care

ACOG in concert with the American Academy of Pediatrics produce guidelines that are updated as necessary concerning prenatal care recommendations (Freeman & Poland, 1992). These directives along with inputs from various regulating agencies and organizations attempt to ensure the delivery of quality prenatal care. This same standardization of care is performed by the ADA for the diabetic population (ADA, 1989). Screening for glucose intolerance is recommended for pregnant women by ACOG (1994), NDDG, and ADA based upon selective screening while others (Coustan, 1994; Moore, 1994) advocate universal screening of all pregnant women for glucose intolerance. The ADA sets standards for diagnosis of GDM based upon results of an OGTT (ADA, 1995b). Growing evidence correlates maternal glycemic control during pregnancy to perinatal outcomes that may have life long repercussions on the health of both mother and baby.

Therapeutic strategies recommended by the ADA for treatment of GDM include close observation of mother and fetus through monitoring of fasting and postprandial

glucose values by SMBG (ADA, 1995a). The need for nutritional counseling, diet management, and insulin therapy for euglycemic control not attainable by diet alone is detailed by an ADA position statement.

Prenatal Care

Early, regular prenatal care results in healthier babies (Freeman & Poland, 1992). Improved perinatal morbidity rates could be achieved by facilitating access to needed resources early and continuously for the childbearing family (Maloni et al., 1996). In America, one in six American women receive inadequate prenatal care although prenatal care is recognized as cost effective (Norwood, 1994). Adequate prenatal care is defined as care beginning during the first trimester of pregnancy and continuing on a regular basis, every four weeks until 28 weeks' gestation, then every two weeks until the 36th week of gestation, and at least weekly until delivery based on the mothers risk status (Freeman & Poland, 1992).

Maternal Weight Gain

Optimal weight gain during pregnancy is a very gradual process (ADA, 1995d). During the first trimester a weight gain of 2 to 5 pounds is expected to compensate for the growth of the uterus and the increased blood volume. This is followed during the second trimester by major physiological changes in the mother's body to support the pregnancy averaging approximately 0.5 to 1 pound per week. This rate of weight gain is continued into the third trimester but now represents changes in the placenta and growth of the baby. For women entering pregnancy weighing within the desirable weight for

height range, gains of 25 to 35 pounds during the pregnancy have been associated with positive outcomes (Hollingsworth, 1992).

Glycosylated Hemoglobin ($HgbA_{1c}$) Value

Glycosylated hemoglobin ($HgbA_{1c}$) values provide an integration of ambient blood glucose levels over a period of 4 - 6 weeks preceding the date of the specimen (ADA, 1995). Although not useful as a screening or diagnostic tool for GDM it may be used as a baseline value in the pregnancy and as a method to compare the severity of the GDM. If the value is in the nondiabetic range it serves as a reassurance that the elevated glucose was probably not present during the critical organogenesis period. If the value is elevated the possibility of Type II diabetes can be introduced and fetal surveillance can be increased.

Neonatal Birth Weight

Use of normative standards to compare data sets was developed when it was determined that birth weight alone did not reflect abnormal growth (Varner, 1994). The Colorado "growth charts" first published in 1963 (Lubchenco, Hansman, Dressler, & Boyd) continue to be the most frequently used set of norms, birth weight percentiles according to gestational age and gender, to compare data sets. Arbuckle and colleagues (1993) contend birth weight norms should be updated every 5 to 10 years. After reviewing over one million births they demonstrated how Canadian birth weight norms shifted to higher birth weights from 1986-1988 when compared to birth weights from

1970 to 1972. Studies that use the term macrosomia generally refer to a weight greater than 4 kilograms and do not use birth weight percentiles (Hod et al., 1991).

Harlass and colleagues (1991) compared the results of OGTT using a 50-gram oral glucose screening tests 1 to 2 weeks apart and found no difference in the mean birth weights of babies born to mothers whose OGTT results were abnormal than from those who tested normal on both occasions. Other factors such as race, age, parity, sex, and especially maternal weight, far outweighed glucose intolerance in determining birth weight. Oats, Abell, Beischer, and Broomhall (1980) could not find a significant association between glucose levels and birth weight until birth weight exceeded the 90th percentile. Even then, 77 percent of women had normal glucose tolerance. The incidence of macrosomia among women with GDM is about 5 % making the value of universal screening to reduce this problem alone of limited value. No evidence exists that reducing birth weights will reduce birth trauma since the vast majority of macrosomic infants are born without birth trauma (Coustan & Imarah, 1984).

Treatment Pros and Cons

Little evidence exists that the management of GDM succeeds. As mentioned above, macrosomia is associated with maternal weight, age, race, parity, and male fetus. According to Stephenson, there have been only four randomized trials of diet or diet and insulin (1993). All were flawed and taken together achieved a reduction in birth weight of 87 grams, a benefit "of questionable clinical significance" (p. 281). Non-randomized trials show that diet modification rarely works without severely limiting calories or the liberal or universal use of insulin. Even where it does work, only two studies of GDM

management reduced operative delivery or cesarean rates to reasonable levels, the main point of preventing macrosomia (Coustan & Imarah, 1984; Langer et al., 1994). In both studies, physicians knew which women were treated and which were controls. If they believed their therapy prevented macrosomia, which other work shows they did, this belief could well have influenced management decisions (Moore, 1994). Another study demonstrated that perinatal outcomes of GDM women could mirror those present in the general population when blood glucose was tightly controlled (Thompson, Dansereau, Creed, & Ridell, 1994).

Management of GDM offers little benefit compared to the risks confirmed. The cesarean rate in a population of gestational diabetics cared for by midwives was 9 percent to 11 percent, including women transferred to obstetric management, or about half the primary cesarean rate reported in populations managed by obstetricians in the same or an earlier time period (O'Brien & Gilson, 1987). GDM group had one-third more cesareans compared with a matched population with normal glucose tolerance, although birth weights were similar (Goldman et al., 1991). In another study, gestational diabetics were randomly assigned to insulin or standard treatment in the third trimester in an effort to minimize macrosomia. Insulin reduced LGA rates to 13 percent compared with LGA rates of 45 percent in the diet group and 38 percent in the group that refused randomization. Despite this, cesarean rates were 14 percent and 21 percent in the diet-treated groups versus 43 percent in the insulin-treated group, a difference attributed to transferring women on insulin to the high-risk service (Buchanan et al, 1994). Many doctors view high cesarean rates as a reasonable trade-off for preventing shoulder

dystocia. This ignores the fact that many shoulder dystocias occur in non-macrosomic infants (Keller 1991) and that the increase in cesarean rate for infants weighing over 4000 g has not improved outcomes (Boyd, Usher, & McLean, 1983) not to mention the role typical obstetric management plays in causing shoulder dystocia.

Increased likelihood of cesarean is not the only risk of GDM management. Insulin increases the risk of SGA babies and causes symptomatic hypoglycemic episodes (Buchanan et al., 1994; Langer et al., 1994). Reducing calories by more than one-third in overweight gestational diabetics causes ketosis (Knoop, Magee, Raisys, & Benedetti, 1991). Finally, the poor predictability of the fetal weight estimates and surveillance tests doctors feel obliged to order, even the belief that GDM is a high-risk condition, undoubtedly lead to countless unnecessary inductions and operative deliveries. Prenatal clinics report 8 % of normal newborn term infants weigh > 4000 grams (Hollingsworth, 1992).

Diagnosis and treatment of GDM is also controversial. After showing that current cutoffs fail to discriminate a group of women at high risk for macrosomia, obstetricians concluded that they should lower the values or that insulin should be given to more women or that cutoffs should be chosen by proclamation (Neiger & Coustan, 1991; Sacks et al. 1995; Tallarigo et al. 1986; Weiner, 1988). Researchers disregarded the ability of sonography to estimate fetal weight for prediction of macrosomia and recommended it anyway (Combs, Singh, & Khoury, 1993). Doctors find that rigid glycemic control did not improve infant outcomes and assume that means they should try harder (Hod et al., 1991).

Summary

In response to the nation's need to contain costs and improve care, health care for pregnant women at high risk is changing. Case management is one model that seeks prevention of adverse outcomes. Women diagnosed with gestational diabetes are at increased risk for developing Type II diabetes mellitus (Damm, 1996; O'Sullivan et al., 1974) Children born to women with GDM are also at risk for complications from birth to adulthood (Hawthorn et al, 1994; Hollingsworth, 1992; Pettitt et al.,1991; Tallarigo et al.,1986). Most women with GDM can control their blood glucose levels through a combination of diet and exercise (ADA, 1995d). The long-term risk of developing diabetes mellitus can also be delayed or avoided by lifestyle changes. Increased surveillance of women with GDM postpartumly and creation of effective methods to encourage education and adoption of lifestyle modifications can reduce the incidence of diabetes mellitus (Hare, 1989; Moore, 1994).

CHAPTER 3

METHODOLOGY

This chapter presents a description of the methods used for data collection and analysis of the process and outcomes associated with an interdisciplinary program for women with gestational diabetes. The research design, setting, sample, and data collection plan are delineated. Protection of human subjects and the data analysis plan are also presented.

Research Design

This research was a descriptive study using retrospective chart reviews. Descriptive research enables greater understanding of a subject and activities surrounding that subject (Polit & Hungler, 1995). This study described how the process of case management was carried out in an interdisciplinary gestational diabetes program and reported perinatal outcomes of the program participants.

Setting

This study occurred in a tertiary care center which was also a regional referral center for portions of the southwestern US. The center has approximately 300 beds and is a teaching facility for several health professions. Outpatient services are provided predominately by an administratively separate but co-located group of physicians who are faculty in the school of medicine and have privileges to practice at the inpatient facility. Medical residents, medical students and students from other health care disciplines participate in the patients care.

OB/GYN clinic services are located on the same floor as labor and delivery. The clinic is capable of performing outpatient testing such as obstetrical ultrasounds, doppler umbilical wave form testing, and nonstress testing. Genetic counseling is also available. Routine laboratory testing is performed elsewhere in the facility. Diabetes in Pregnancy Clinic (DPC) is offered once a week to clinic patients.

Members of the DPC provide diabetes education and management using an interdisciplinary team approach. The team is composed of physicians, medical residents, medical students, nurses, dietitians, and social workers as needed. The dietitian is the only certified diabetic educator (CDE) on the team. The clinic director, a perinatologist, completed a fellowship at a major referral center in the New England area for diabetes in pregnancy. Medical residents and medical students provide services on a rotational basis. Clinic nurses are permanently assigned to the DPC and are prepared at the baccalaureate level in nursing. The perinatal case manager is a master's prepared nurse. All of these nurses are participating in a course to become CDEs.

Antepartum records are updated weekly by the clinic nurses to ensure all requested results are available, list testing that must be accomplished during the next clinic visit, and relate the status of requested reports. A perinatologist, OB/GYN Chief Clinical Resident, and other members of the interdisciplinary team review the program participants' records during DPC rounds just prior to the clinic. DPC rounds consists of a review of clinical history, average fasting and postprandial blood glucose values during the previous week, $HgbA_{1c}$ values, referral needs or results, results of surveillance

measures, and psychosocial information. Information, suggestions, and ideas on specific issues are sought from expert team members. A care plan is then established for each patient which includes short-term and long-term goals. Information on DPC patients who are hospitalized or who have delivered is provided by the obstetrical residents and the perinatal nurse case manager.

Program participants arrive for a lengthy initial appointment. Often the women are accompanied by significant others who are curious regarding the diagnosis of GDM and wish to participate in the plan of care. An average of one new patient is oriented each week. A list on the antepartum record indicates which team members patients are expected to see. This initial visit includes the perinatologist, medical resident, clinic nurses, dietitian, and nurse case manager. Team members are crossed off the list as each step is accomplished to facilitate movement through the process and to ensure no team member is missed.

To begin the process, a physician discusses with the participant her specific health care needs, outlines an initial plan of care based on her 3-hour OGTT, and relates the activities to occur during the first visit. The woman watches a video on diabetes mellitus, GDM, treatment regimes, and signs and symptoms of potential problems. One of the two permanently assigned clinic nurses will then answer any questions and provide preprinted information regarding GDM, dietary allowances, and treatment of GDM with diet and/or insulin therapy. This nurse provides hands-on training for self-monitoring of blood glucose (SMBG) performance using a memory-based reflectance monitor as well

as insulin administration if and when this therapy is required. The reflectance monitors are provided via a loan program to each client.

A visit with the dietitian includes a listing of preferred foods, current meal times, and calculation of the woman's BMI. In an effort to prevent excess weight gain a tentative meal plan which eliminates sources of concentrated sugars is determined. The importance of eating at scheduled intervals is reviewed as well as testing for SMBG at designated times. The women are encouraged to keep a diet log and to annotate any unusual diet or activity on their glucose log.

The perinatal NCMr informs the woman about available services, reviews programs the woman may not be aware she is eligible for and explains her role as a member of the interdisciplinary team. Any team member may request a consultation for the woman with a social worker.

Final review of the antepartum record for completeness is performed by the clinic nurses. The need for special appointments and referrals is documented to assist the administrative staff in scheduling needs. These nurses also ensure the women are aware of how to contact the clinic if questions arise or obtain medical care during and after normal office hours.

During subsequent clinic visits the client sees the clinic nurse, physicians (OB residents or family practice resident who consult with a perinatologist and may be accompanied by a medical student) and nurse case manager routinely. Other team members are seen as needed. Weekly weights, blood pressures, urine evaluation for ketones and protein are performed. The hand written glucose logs are compared to the

memory-based reflectance meter for accuracy of time, date, and glucose value recordings. Any deviations or missing information are noted and discussed with the patient. Use of other glucometers, difficulty obtaining glucometer values or lack of knowledge regarding how the logs affect their treatment is addressed. Glucose log data are downloaded weekly. Graphs and pie charts of the blood glucose values reflecting compliance with target glucose values are printed out weekly and available to the patient and team members to use. The pie charts are given to the patient to show percentage of within, above and below target blood glucose values divided into meal times as a method of reinforcement.

Sample

Women in the DPC have either preexisiting diabetes mellitus (Type I and II) or GDM. Only women with GDM were included in this study. Screening for diabetes occurs between 24 to 28 weeks' gestation. Women enrolled in this study had elevated 1-hour OGTT and at least two elevations in a 3-hour OGTT.

All women with GDM who participated in the DPC from January, 1996 through February, 1997, comprised the sample. An estimated 25 to 30 women were anticipated in study. Women excluded from this study included those who transferred antepartum care to another clinic prior to delivery, delivered prior to 35 weeks' gestation, had a multiple pregnancy, delivered at a facility other than the one under study, refused to use the memory-based reflectance meters, or those whose primary language was not Spanish or English. Women were not excluded for gravity, parity, or presence of other underlying disease.

Data Related to Process

Data to document the process were obtained from the maternal antepartum and delivery record. Information on the frequency of DPC appointments, specific providers seen, length of pregnancy cared for in the clinic, treatment, referrals made, and reports from the referral source or patient indicating contact with the referral source are contained in the maternal record.

Data Related to Outcome

Outcome data were found in both the maternal and the neonatal record. Information on estimated gestation age (EGA), maternal blood glucose, maternal weight gain and shoulder dystocia during delivery were found in the maternal record. The newborn's record provided data on birth weight, EGA, shoulder dystocia during delivery and hypoglycemia or hypocalcemia during transition to extrauterine life.

Data Collection

Data for this study were obtained by a retrospective chart review. The names of women with GDM who attended DPC were provided by the interdisciplinary team NCMr. The investigator obtained the medical records (combined outpatient and inpatient record) from the Medical Records Department after the eligible women were discharged from the hospital. Data were recorded by the investigator on a GDM Interdisciplinary Team Data Collection Tool (Appendix A). This tool consisted of 5 fill-in the blank questions for process data from the maternal record. Outcome data were obtained using 11 questions from the maternal and neonatal records.

Accuracy of data transcription was confirmed by an audit of at least 10 percent of the records chosen at random. The auditor was an impartial non-medical individual trained by the investigator to serve as a secondary rater. Polit and Hungler (1995) define interrater reliability as the ratio of agreement between two raters who separately evaluate an event and assign the same ratings to the event. Interrater reliability of 90 percent or greater on question numbers 1, 7, 15, and 16 of the GDM Interdisciplinary Team Data Collection Tool was considered acceptable for this study. Failure to obtain 90 percent interrater reliability would have necessitated further training sessions until the 90 percent agreement goal was obtained in another 10 percent of the records. The following equation was used to calculate agreement:

$$\frac{\text{Number of agreements}}{\text{Number of agreements + disagreements}} \times 100 = \%\ \text{Agreement}$$

Protection of Human Subjects

Pregnant women and infants are vulnerable subjects (Polit & Hungler, 1995) and require increased scrutiny as research subjects to protect privacy and minimize risks. The proposed research project received approval by the Human Subjects Committee at the University of Arizona (Appendix B). Permission to access medical records came from the University Medical Center (UMC) Conditions of Admission to UMC Hospital form and the UMC Medical Records Department (Appendix B). This form is signed by the pregnant woman or significant other upon admission to the hospital and in accordance with hospital policy. Section 5. Part e of this form states "authorization is granted to release information" from the patient's Hospital records "as necessary or

appropriate for medical education and research." Confidentiality was maintained by utilizing the subjects' hospital numbers until data collection was completed and an interrater reliability of at least 90 percent was established. Hospital numbers were removed prior to data analysis to ensure confidentiality of data.

Data Analysis Plan

Descriptive statistics, including measures of central tendency and dispersion, were used to analyze the data from interval, categorical, and ratio measurements. The statistics were manually calculated. Graphs and narrative summaries of the results characterize the findings.

Summary

This chapter discussed the methods used in answering the proposed research questions related to the process, and outcomes of the interdisciplinary DPC program. Presentation and analysis of data was also presented in this chapter.

CHAPTER 4

RESULTS

Study findings are presented in this section. Demographic characteristics of the sample are described. Interrater reliability to establish the reliability of the data collection is reported. Each research question is then addressed separately. This chapter is concluded with a summary of research findings.

Demographic Characteristics of the Sample

Fifty-two names of women who participated in the DPC were provided by the NCMr to the researcher. Out of these 52 women, 13 women were undelivered, 14 women had pregestational diabetes, one woman moved out of the state, and one woman delivered at another hospital. The remaining 23 women met eligibility criteria. However, six of the maternal records did not contain self-monitoring glucose logs or documentation of clinic appointments in the DPC which were required for study inclusion. The final sample size was 17 women with GDM who participated in the DPC and whose records contained self-monitoring glucose logs and documentation regarding clinic appointments with the DPC.

Demographic data for the seventeen women with GDM are depicted in Table 1. The ages of the women ranged from 18 to 39 years of age ($\underline{M} = 29.6$, $\underline{SD} = 6.8$). The median age was 30 years. The number of pregnancies for the women ranged from 1 to 8 pregnancies ($\underline{M} = 3.4$, $\underline{Mdn} = 3$, $\underline{SD} = 2.4$). While the number of pregnancies that reached viability for these women ranged from 1 to 6 pregnancies ($\underline{M} = 2.6$, $\underline{Mdn} = 2$, $\underline{SD}$

Table 1

Demographic Data of the Study Sample (N = 17)

Variable	Values	Range	M	SD
Age in years	18-39	21	29.6	6.8
Gravidity	1-8	7	3.4	2.4
Parity	1-6	5	2.6	1.7
Weeks' Gestation	36.2-41.1*	5.1*	38.4*	2.0*

Note. M = mean, SD = standard deviation, * based on units of 7 versus units of 10

= 1.7). The number of weeks' gestation at the time of delivery ranged from 36.2 to 41.1 weeks. The median number of weeks' gestation was 38.3 weeks (M = 38.43, SD = 2.01).

Other demographic characteristics of the sample are found in Table 2. Ethnicity was 41 % Hispanic (n = 7), 35 % Caucasian (n = 6), 18 % African American (n = 3), and 6 % Asian (n = 1). The marital status included 11 married (65 %), 5 single (29 %), and 1 divorced (6 %). Treatment methods for these women consisted of diet only (n = 12, 71 %) or diet and insulin (n = 5, 29%). The primary method of delivery was spontaneous vaginal delivery (n = 10, 58%). Vaginal delivery was followed, in rank order, by repeat cesarean section (n = 3, 18%), primary cesarean section (n = 2, 12%), and vaginal delivery after cesarean section (n = 2, 12%).

Interrater Reliability

An impartial non-medical individual trained by the investigator served as a

Table 2

Characteristics of the Study Sample (N = 17)

Characteristic	Category	n	Percentage
Ethnicity	Hispanic	7	41
	Caucasian	6	35
	African American	3	18
	Asian	1	6
Marital Status	Married	11	65
	Single	5	29
	Divorced	1	6
Treatment Method	Diet	12	71
	Diet and Insulin	5	29
Delivery Method	Spontaneous Vaginal Delivery	10	58
	Primary Cesarean Section	3	18
	Repeat Cesarean Section	2	12
	Vaginal Birth after Cesarean Section	2	12

Note. n = number in a subsample

secondary rater to ensure accuracy of data transcription. All medical records numbers were placed in a container in order to randomly select records to audit. Five medical record numbers were selected for a 15% audit of the combined 34 mother and baby medical records. The number of agreements for responses to question numbers 1, 7, 15,and 16 of the GDM Interdisciplinary Team Data Collection Tool were 20 out of 20 possible agreements. An interrater reliability of 100 percent was achieved which exceeded the desired minimum acceptance rate of 90 percent.

Research Questions

This study was designed to describe an interdisciplinary gestational diabetes program by answering questions related to process and outcome. The findings of this study are organized in order of the research questions asked. Those questions related to process will be answered first followed by the questions related to outcome.

Related to Process:

Question #1. How many DPC visits did program participants attend?

Program participants attended 9.1 DPC visits on the average (SD = 4.0). The number of visits ranged from a low of 3 to a high of 16 with a median number of 8 visits (Figure 2).

Question #2. What was the period of contact for the participants attending the DPC?

Participants were first seen in the DPC during their pregnancies from 25.2 to 37.6 weeks' gestation (median of 35.3 weeks). Women with GDM were seen in the clinic for an average of 7.4 weeks' gestation (SD = 6.0) with a median of 7 weeks' gestation. Some of the women in the program were seen in the DPC over a 3 week period during their pregnancy (12 %) while others were seen over a 14 week period (88 %). The period of contact for the participants normally occurred up to the time of delivery although 3 women (18 %) did not attend scheduled appointments at the end of their pregnancies. The frequency of DPC visits was generally higher for women with longer periods of contact (Figure 3).

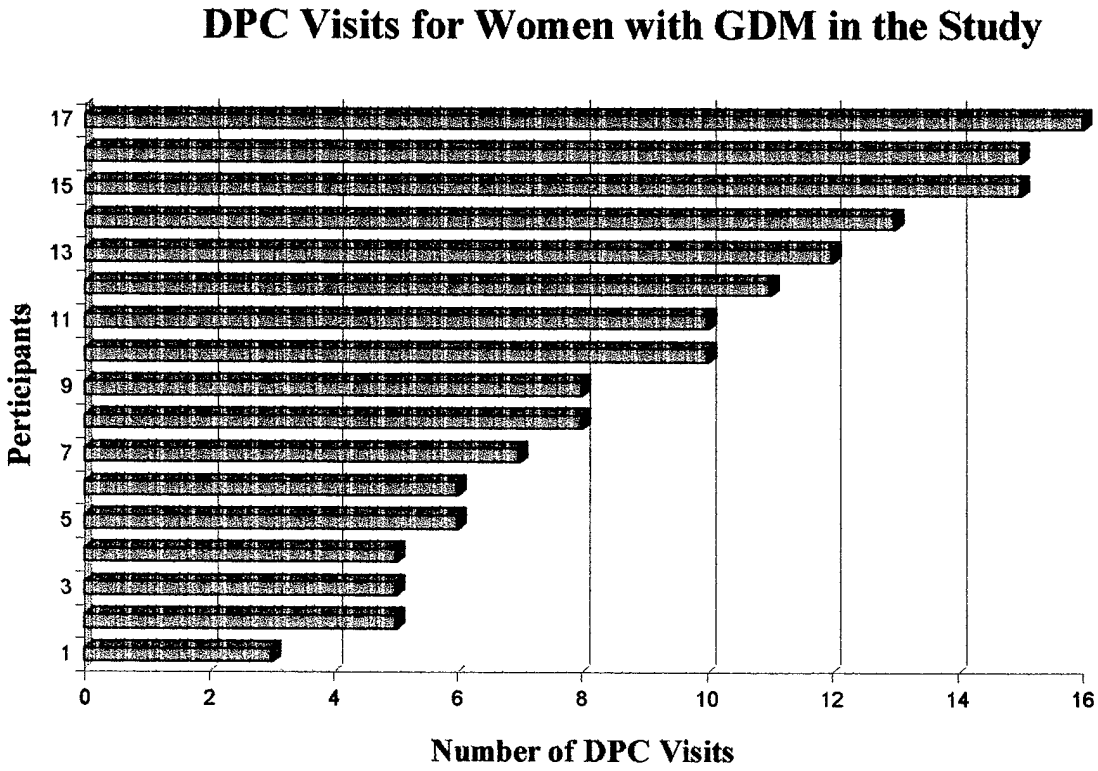

Figure 2. Diabetes in Pregnancy Clinic Visits for Women with Gestational Diabetes Mellitus in the Study

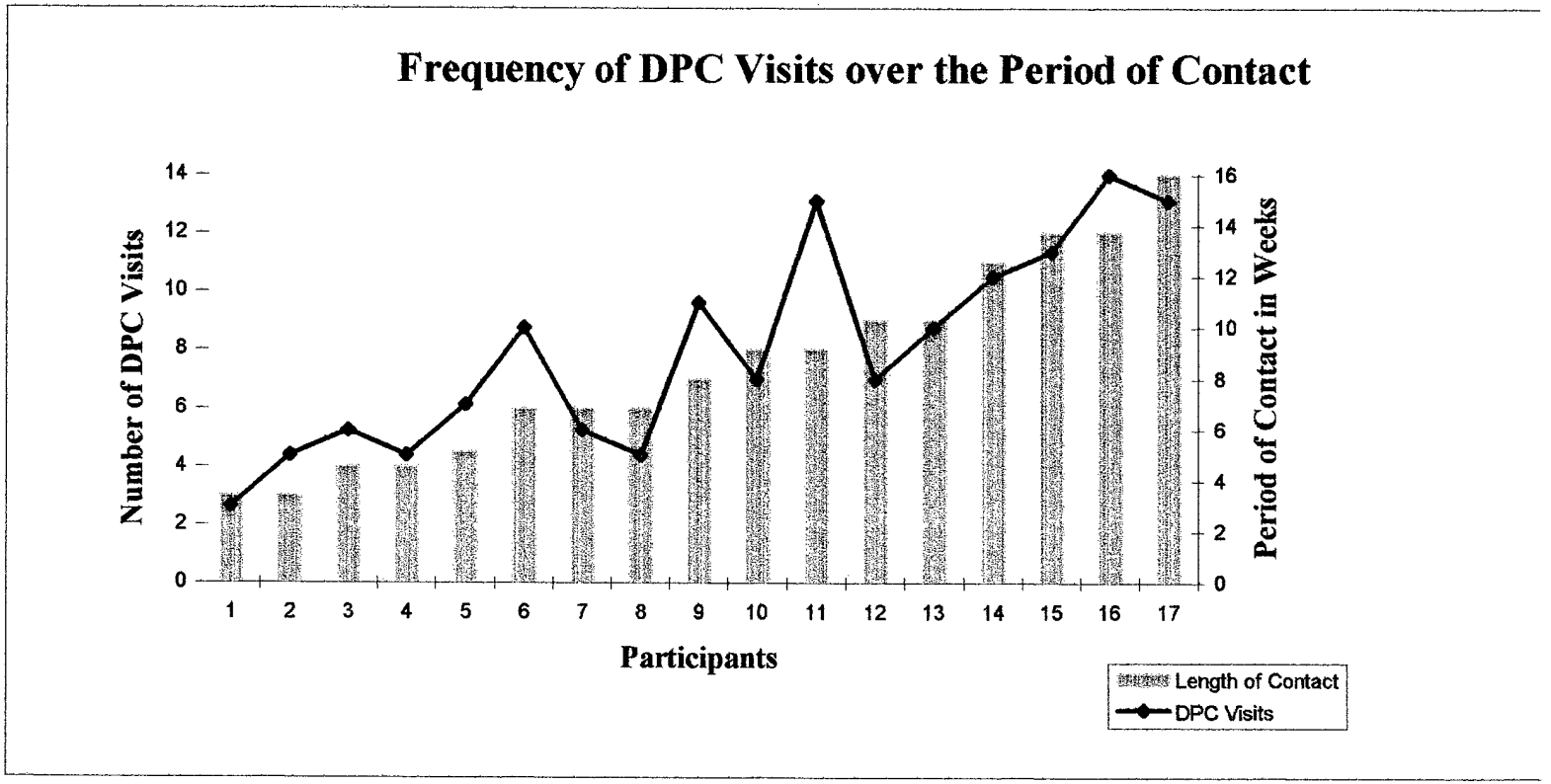

Figure 3. Frequency of Diabetes in Pregnancy Clinic Visits over the Period of Contact

Question #3. With what frequency did each member of the interdisciplinary team interact with participants over the duration of the pregnancy?

On the average 17 participants met with members of the interdisciplinary team 19.5 times (SD = 9.95). The total number of interactions was 332 over 126.5 weeks. Table 3 provides data on interactions for each participant.

How many times did the patient see the perinatologist? For one participant no clinic visit with the perinatologist was documented. The researcher was unable to link any clinic visit notes to perinatologists attached to the DPC. The range of interactions was from 0 to 15. On the average the women saw the perinatologist 6.2 times (SD = 3.52). The perinatologists had more interactions with the women in the study then the other team members.

How many times did the patient see the senior resident? After the perinatologist, the women with GDM saw the senior resident most often (M = 5.4). The interactions of the senior resident with the women varied from 1 to 11 times during the period of contact.

How many times did the patient see the resident? Women saw the resident an average of 2.6 times prior to delivery. The patients saw the non senior residents as few as never, in the case of one patient by request. The patient with the most visits to the DPC, 16 total, saw the resident the most, 8 times.

How many times did the patient see one of the clinic RNs? The two clinic RNs who provided the initial diabetes education saw each of the women with GDM.

Table 3

Frequency of Interactions with Various Interdisciplinary Team Members by Length of Contact in Weeks

Contact length	DPC visits	Perinatologist	Senior Resident	Resident	Clinic RNs	Dietitian	NCMr	Treatment
3	3	0	3	1	5	1	0	Diet
3	5	1	1	0	2	0	0	Insulin
4	5	4	5	2	2	1	0	Diet
4	6	6	5	2	2	0	1	Diet
4.5	7	7	4	3	4	1	0	Diet
6	5	6	3	1	3	1	2	Diet
6	6	5	3	1	2	0	0	Diet
6	10	4	5	3	2	1	0	Diet
7	11	8	4	4	4	2	0	Insulin
8	8	7	2	1	2	4	0	Diet
8	15	6	5	3	2	0	0	Insulin
9	8	2	5	0	2	1	0	Diet
9	10	8	6	3	1	5	1	Diet
11	12	8	11	5	5	4	2	Insulin
12	16	9	10	8	4	3	2	Insulin
12	13	9	11	4	2	1	3	Diet
14	15	15	9	4	4	2	4	Diet
7.4	9.1	6.2	5.4	2.6	2.8	1.6	0.9	Mean

Note. DPC = Diabetes in Pregnancy Clinic, RNs = Registered Nurses, NCMr = Nurse Case Manager, Insulin = Diet & Insulin

Interactions with the two clinic RNs ranged from one to five times over the period of contact for the women in this study (M = 2.8).

How many times did the patient see the Dietitian? Four patients never saw the dietitian. Of these four, two were treated with diet only and two were treated with diet and insulin. The contact length for the patients not seen by the dietitian varied from 3 to 8 weeks. Those women who saw the dietitian did so on the average, 2.1 times. One patient saw the dietitian 5 times during her period of contact.

How many times did the patient see the Perinatal NCMr? The average number of interactions between the 17 women and the NCMr was 0.9 (Mdn = 0, range = 0 - 4, SD = 1.3). Ten patients did not have documented interactions with the NCMr. The seven women who did interact with the NCMr averaged 2.1 times (Mdn = 2, range = 1 - 4, SD = 1.1).

Question #4. What percentage of participants were referred to resources not provided by the interdisciplinary team?

Nine out of 17 patients (53 %) were referred to resources outside of those provided by the interdisciplinary team. The number of times these nine women were referred to resources ranged from 1 to 5 (M = 1.7, Mdn = 1, SD = 1.32). The majority of referrals were for genetic counseling. Other referral sources were social services, internal medicine, pool therapy, and home health for nonstress tests and glucose monitoring.

Question #5. What percentage of time were the participants compliant in seeking the recommended referrals?

Of the 9 women in the study who were referred to other sources referrals were sought by 87 % (13 out of 15 possible referrals).

Question #6. How many participants were treated with diet alone?

Twelve participants (71 %) were treated with diet therapy alone (Table 3).

Question #7. How many participants were treated with diet and insulin therapy?

Five of the participants (29 %) were treated with diet and insulin therapy (Table3).

Related to Outcomes:

Question #8. What was the maternal weight gain during pregnancy for participants?

One study participant had no documented weight prior to pregnancy or statement of weight gained during pregnancy. For the 16 women with valid data, weight gained during pregnancy ranged from 1 to 77 pounds. The median weight gain was 31 pounds ($M = 33.3$, $SD = 18.9$).

Question #9. What was the number of blood glucose values obtained on a daily basis by participants during the four week period (28 days) prior to delivery? A total of 1,241 blood glucose values were obtained by 15 participants during the 4 weeks and 2 participants during the 3 weeks prior to delivery ($M = 73$, $Mdn = 86$, range = 79, $SD = 30.9$). An average of 2.7 blood glucose measurements per day were obtained by the participants (Figure 4).

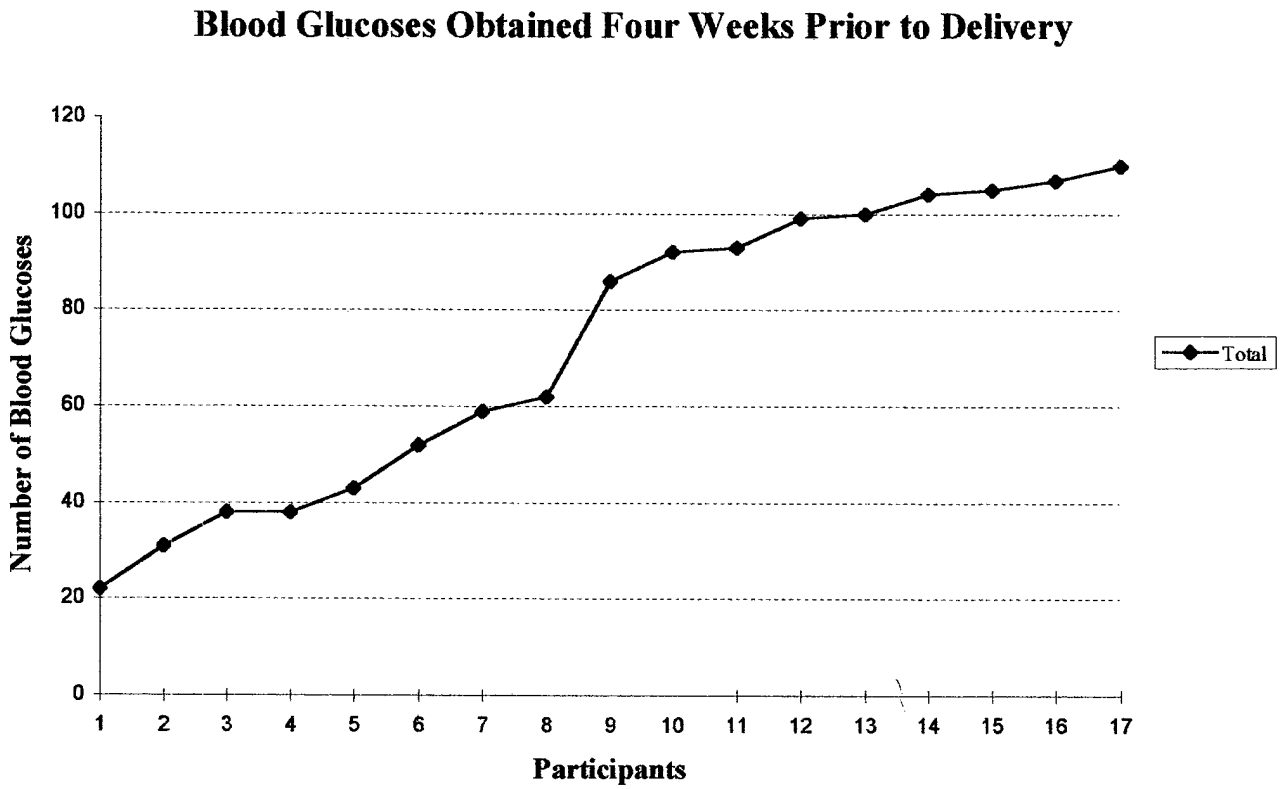

Figure 4. Blood Glucose Values Obtained by Participants During the Four Weeks Prior to Delivery

Question #10. What were the last seven fasting blood glucose values obtained for the participants prior to delivery?

The last seven fasting blood glucose values for program participants averaged 81.4 mg/dL (Mdn = 83.4 mg/dL, range = 67-91.3 mg/dL, SD = 6.87 mg/dL). This average value was between the targeted values of 60 to 100 mg/dL for fasting blood glucose. Participants obtained 112 fasting blood glucose values during the 7 days prior to delivery (Figure 5). During the week prior to delivery participants obtained more fasting blood glucose evaluations (a rate of 94.1 %, n = 112, M = 6.6, SD = 1.5, range = 1-7, Mdn = 7) than any of the postprandial evaluations.

Question #11. What were the last seven days' postprandial blood glucose values obtained for the participants prior to delivery?

A total of 301 postprandial values (84.3 % of possible values) were obtained during the 7 days prior to delivery. The median number of postprandial values obtained was 6 for all three meal periods. More values were obtained after lunch (85.7 %, n = 102, M = 6, SD = 0.94, range = 5-7) than after breakfast (84.9 %, n = 101, M = 5.9, SD = 1.0, range = 4-7). The least number of values was obtained after dinner (82.4 %, n = 98, M = 5.8, SD = 1.2, range = 3-7). The number of values obtained by participants during the week prior to delivery decreased as the time of their delivery drew closer. During this time period the average postprandial breakfast blood glucose values obtained were 98 mg/dL (n = 101 values, Mdn = 95 mg/dL, range = 70.4-117.1 mg/dL, SD = 13.03). Average lunch postprandial blood glucose values for the 7 days prior to delivery were higher at 100.5 mg/dL (n = 102, Mdn = 95.4 mg/dL, range = 88-118 mg/dL, SD = 10.33).

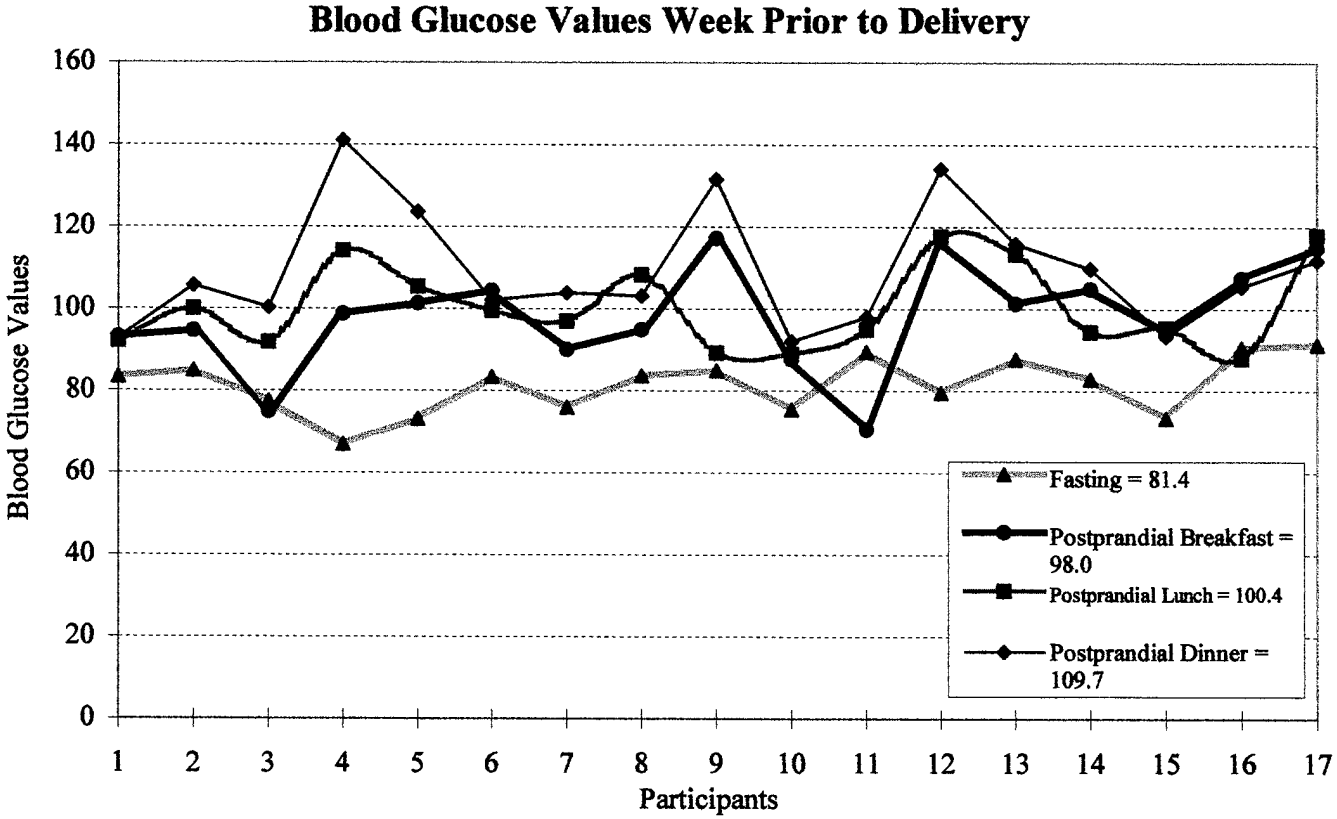

Figure 5. Blood Glucose Values for Women with GDM in Study Sample Week Prior to Delivery

The highest postprandial blood glucose values obtained during the 7 days prior to delivery occurred after dinner, 109.7 mg/dL (n = 98, Mdn = 103.8 mg/dL, range = 92-141 mg/dL, SD = 14.89).

Average postprandial breakfast, lunch, and dinner values were generally within the 80 to 120 mg/dL targeted range. Two average postprandial breakfast values were below 80, 70.4 and 75, and four average postprandial dinner values were above 120, 123.5, 131.4, 134.2, and 141. Out of these six deviations from the targeted values only two women with elevated postprandial values were on diet and insulin therapy. Overall, the mean blood glucose was 97.38 mg/dL for the participants (Table 4). The participants treated with diet only had lower blood glucose values than the participants treated with diet and insulin.

Question #12. What were the glycosylated hemoglobin ($HgbA_{1c}$) values for the program participants at program enrollment and at program completion?

Only three women had $HgbA_{1c}$ values drawn. Two women had values drawn at delivery only. These values were 6.1 % (infant weighed 4230 grams) and 4.5 % (infant weighed 4130 grams). One of the program participants had two $HgbA_{1c}$ values drawn. The values were 7.3 % initially followed by a value of 6.9 % at the time of delivery. This woman's newborn weighed 4290 grams.

Question #13. What were the birth weights and birth percentile (using gestational age) of the offspring born to program participants?

Table 4

Average Maternal Blood Glucose Values in mg/dl 7 Days Prior to Delivery

Participant Subsamples	Fasting	Postprandial Breakfast	Postprandial Lunch	Postprandial Dinner
Bore AGA Newborns	81.2	97.98	102.62	108.93
Bore LGA Newborns	82.78	97.72	97.7	109.7
Treated with Diet Only	79.17	92.40	98.47	105.44
Treated with Diet and Insulin	86.77	111.45	105.21	119.79
Overall Averages	**Fasting**	**Postprandial Breakfast**	**Postprandial Lunch**	**Postprandial Dinner**
97.38	91.29	115	118	111.86

The average birth weight for the infants born to the women with GDM in the study was 3562.9 grams (Mdn = 3685 grams) and ranged from 2590 to 4545 grams (SD =601.74 grams). Birth weights for AGA infants (n = 10) ranged from 2590 to 3889 grams (Mdn = 3220 grams, SD = 459.34 grams) while birth weights for the LGA infants (n = 7) ranged from 3685 to 4545 grams (Mdn = 4130 grams, SD = 298.38 grams). Three of the LGA infants weighed under the 4000 gram minimum for macrosomia as defined by weight alone (Figure 6).

Participants treated with diet and insulin therapy (n = 5) gave birth to LGA infants 60 % of the time (Figure 7). The remaining twelve participants who were treated with diet therapy alone gave birth to LGA infants 33 % of the time. An overall LGA rate of 41 % occurred in the DPC group. None of the infants born to the participants were SGA.

Question #14. What were the incidences of newborn complications such as hypoglycemia, hypocalcemia, and shoulder dystocia occurring in program participants?

Hypoglycemia was documented for one infant and shoulder dystocia for another newborn (5.9 %). No calcium values were ordered or obtained on any infants. Incidence of hypocalcemia could not be assessed.

Summary

Descriptive statistics, mean, median, range, and standard deviation, were used to describe the maternal and neonatal outcomes of 17 women with GDM who participated in an interdisciplinary gestational diabetes program. The majority of the women in the sample studied were married (65 %), 29.6 years of age, of Hispanic (41 %) or Caucasian

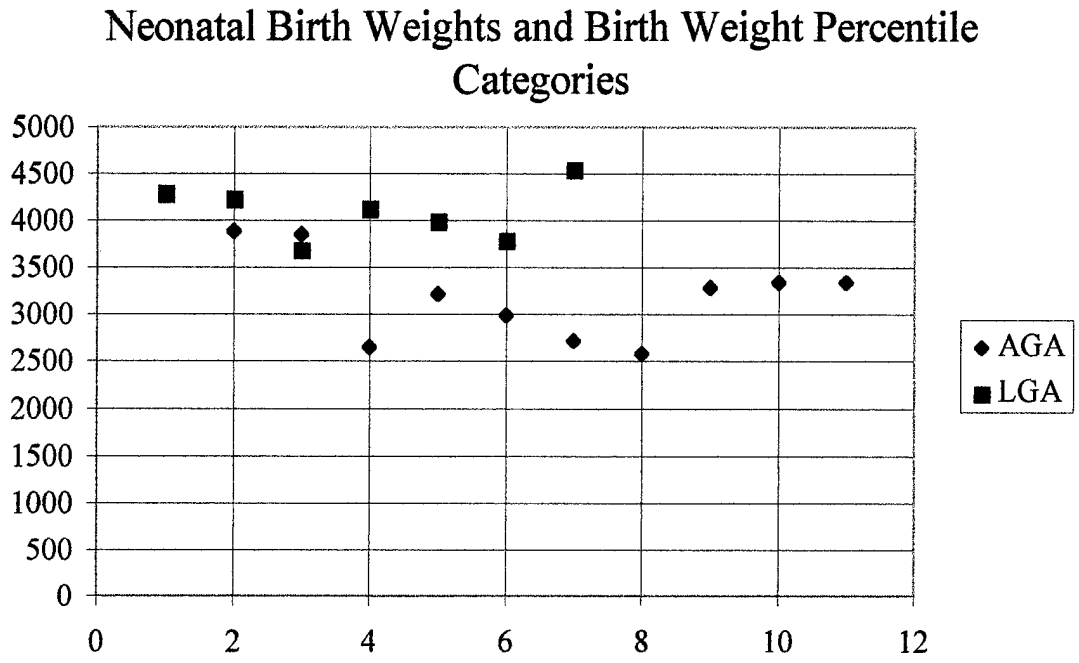

Figure 6. Comparison of Neonatal Birth Weights and Birth Weight Percentile Categories

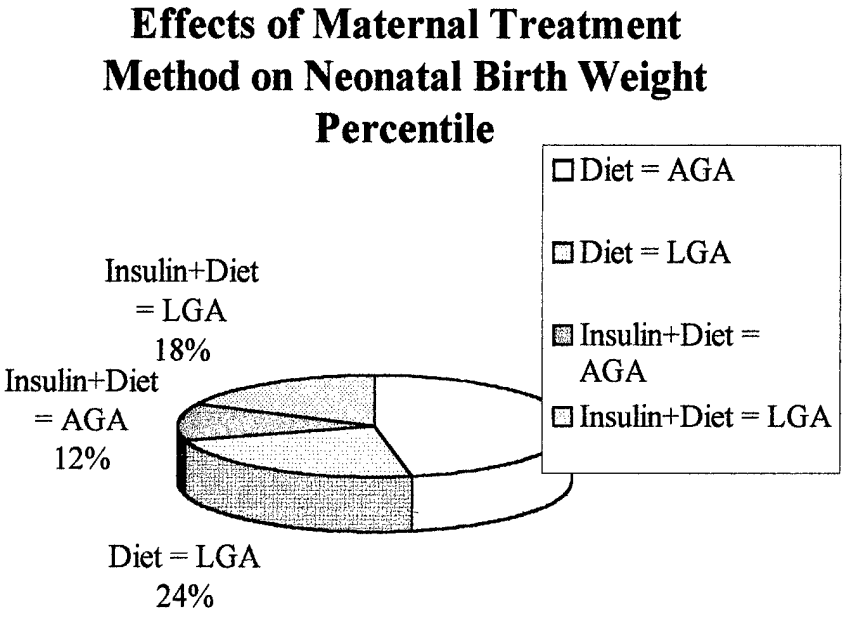

Figure 7. Effects of Maternal Treatment Method on Neonatal Birth Weight Percentile

(35 %) descent, pregnant 3.4 times and carrying 2.6 of these pregnancies to viability. Most of the women were treated with diet therapy (71 %) during their period of contact with the program (M = 7.4 week's gestation). On the average program participants were seen 9.1 times in the DPC. These women were seen most frequently by the perinatologist (M = 6.2) and least by the NCMr (M = 0.9). Fifty- three percent of the participants were referred to resources not provided by the interdisciplinary team which they sought 87 % of the time. Average maternal weight gain was 31 pounds. During the four weeks prior to delivery the women averaged 2.6 of the 4 daily blood glucose measurements requested. The fasting blood glucoses obtained the week prior to delivery averaged 81.4 mg/dL. Postprandial blood glucoses averaged 98mg/dL for breakfast, 100.5 mg/dL for lunch, and 109.7 mg/dL for dinner. Only three of the women in the study sample had $HgbA_{1c}$ values drawn. Newborn complications of hypoglycemia and shoulder dystocia occurred once in two different infants. The incidence of hypocalcemia could not be assessed on any of the newborns.

CHAPTER 5

DISCUSSION

In this concluding chapter the results are considered in relation to the conceptual framework and references cited earlier. After interpreting the findings, the limitations of the study, the implications for nursing case management, and recommendations for future nursing research are discussed.

Interpretation of Findings

Donabedian's structure-process-outcome paradigm was used as the conceptual framework for this study to evaluate the quality of an interdisciplinary case management program as an alternative health care delivery model for women with GDM. The structure of the interdisciplinary program was described in Chapter 3. Process and outcome data will be addressed separately.

Related to Process

Research questions one through seven were used to examine the process of case management employed by the interdisciplinary team. Participants studied, 17 women with GDM, were all seen from program enrollment until delivery.

The number of DPC visits was generally in proportion to the period of contact. This finding would indicate care was continuous over the period of contact. According to Freeman and Poland (1992) continuous care over time may result in healthier babies. Care provided to the women with GDM occurred at a frequency equal to or greater than a frequency that would qualify as adequate (Freeman & Poland). ACOG (1994)

recommended frequent visits as well as telephone follow-up to facilitate optimal glycemic control for patients who require insulin or whose glycemic control is poor. Fifteen of the seventeen women studied were seen at least weekly in the DPC and two other participants were seen one visit less than once per week for an overall average of 1.2 visits per period of contact. McClanahan (1992) stated prenatal care that is continuous throughout a pregnancy may enable the expense of inpatient treatment to be avoided. Only one of the subjects was admitted to the acute care setting during the period of contact for care unrelated to delivery.

The importance of communication to the process of case management is underscored by CMSA's (1995) definition of case management: "... a collaborative process which assesses, plans, implements, coordinates, monitors and evaluates options and services to meet an individual's health needs through communication and available resources to promote quality cost-effective outcomes" (p. 8). Korn (1992) noted appropriately performed case management resulted in more frequent interactions between the provider and the patient. Documentation of interaction between the interdisciplinary case management team members and study participants varied between disciplines. The perinatologist documented the most frequent interactions with program participants and the NCMr documented the least frequent interactions. Although the researcher has working knowledge of weekly interactions between the NCMr and study participants, documentation of these interactions was not available.

Documentation was available on the team's referral of participants to resources not available within the interdisciplinary team and participant's compliance rate with the

referrals. The majority of referrals were for genetic counseling. Other referral sources were social services, internal medicine, pool therapy, and home health for nonstress tests and glucose monitoring.

The ADA (1995d) found dietary management alone could be effective for 75 - 80% of women with GDM. In the sample investigated 71 % were treated with diet therapy alone and the other 29 % received exogenous insulin to facilitate euglycemia. The ADA also recommends all affected women receive nutritional counseling regarding the ADA's proposed recommendations for calorie distribution ideally provided by a registered dietitian (RD). Documentation of dietary education by a RD did not occur for four of the patients in this study (24 %).

Related to Outcome

Research questions eight through fourteen were used to describe the perinatal outcomes of women with GDM who participated in the interdisciplinary gestational diabetes program. Maternal and neonatal outcomes were examined.

Maternal considerations.

Pregnancy weight goals vary between lean (25-35 lb goal) and obese women (15-20 lb goal) (ADA, 1995d; Hollingsworth, 1992). Although participants were not designated as lean or obese their weight was between 115 - 299 lb at the beginning of their pregnancy and 140-300 lb at delivery. The average weight gain for participants was 33.3 lb. Women giving birth to AGA infants had an average weight gain of 33.3 lb and neonatal birth weight of 3257.7 g while women giving birth to LGA infants experienced an average maternal weight gain of 33.1 lb and their neonates weighed an average of

4094.3 g. The women in this study had a greater weight gain than Langer and colleagues' (1994) conventional or conventional GDM management group whose average weight gain was 26 lb.

Several sources noted an association between women with GDM and increased rates of operative deliveries and birth trauma (Bernstein & Catalano, 1994; Coustan & Imarah, 1984). Statistically significant differences in C-section rates were reported by Magee and colleagues (1993) for women with GDM (30.2 %) versus women with negative OGTTs (21.5 %). Goldman and colleagues (1991), as noted in Chapter 2, reported an increased C-section rate for women with GDM (35.3 %) over the rate of a matched population with a normal OGTT (22 %) despite similar birth weights. In a report by Cousins (1987) that covered a 20 year period the overall C-section rate was 20.4 % for women with GDM (n = 1781); 12.4 % primary and 9.8 % repeat operations. For women with GDM in the DPC study sample, the C-section rate was 29.4 %; 11.8 % primary and 17.6 % repeat operations. The C-section rate was 24 % for neonatal birth weight secondary to macrosomia, by definition, and 41 % for LGA. Twelve percent of the women with GDM had vaginal births after C-section (VBAC) and the rate of spontaneous vaginal delivery was 58 %. Women in this study were delivered by repeat operations (18 %) secondary to compound presentation, hand, head, and cord, history of right upper quadrant pain in the presence of an abdominal cerclage, and history of anemia ultimately requiring a hysterectomy for placenta accreta. One primary elective C-section was performed for an estimated fetal weight greater than 4000 g; neonate weighed 4545 g. This participant had the greatest maternal weight gain and was treated

by diet and insulin therapy. The second primary C-section was for a case of active genital herpes lesions.

Moore (1994) claimed the use of surveillance methods could encourage women to maintain their glycemic status within a prespecified range. Average fasting blood glucose evaluations for the DPC study sample were between the targeted values of 60 to 100 mg/dL. Average postprandial breakfast, lunch, and dinner values were generally within the 80 to 120 mg/dL targeted range. Overall, the mean blood glucose was 97.38 mg/dL for the participants.

Langer and colleagues (1994) estimated their conventional GDM management group performed a mean number of 3-4 blood glucose evaluations per day, 4 were requested. The intensified group was asked to perform 7 blood glucose evaluations per day and performed 5. DPC participants performed a mean number of 2.6 blood glucose evaluations during the four week period prior to delivery which increased to 3.7 the week prior to delivery. The number of values obtained by participants during the week prior to delivery steadily decreased as the time of their delivery drew closer.

This study revealed minimum information regarding $HgbA_{1c}$ values for women with GDM. One DPC participant (6 %) had two values drawn and two DPC participants had one value drawn (18 %). Only one of the four $HgbA_{1c}$ values fell into the range Shields and colleagues (1993) termed normal (4-6 %). The birth weights of these three newborns exceeded 4000 g each.

Neonatal considerations.

Participants in the DPC group gave birth to infants whose overall rate of LGA was 41 %. None of the infants born to the participants were SGA. In Langer and colleagues (1994) study overall LGA rates of 20.1 % were documented for the conventionally treated group, both diet only, and diet and insulin therapy groups. The intensified treatment group had an overall LGA rate of 13.1 %, 12.5 % for diet only, and 13.7 % for the diet and insulin group.

Infants of mothers with GDM in this study experienced few of the neonatal complications often associated with GDM (ACOG, 1994; ADA, 1995a; Blank et al., 1995). Macrosomia occurred in these newborns at the rate of 23.5 % ($n = 4$) with no evidence of birth injuries and one documented case of shoulder dystocia. Langer and colleagues (1994) reported 13.6 % incidence of macrosomia for their conventional group, 7.1 % for their intensified group, and 8.1 % for their nondiabetic control group. Boyd (1983) reported an overall macrosomia incidence of 10 % in infants weighing over 2500 g from 1978-1980 and 1963-1965. According to Hod and colleagues (1991) the incidence of macrosomia for women with GDM ranged from 10.1-32 %. Boyd also documented an increase in the incidence of macrosomia related to increasing gestational age. The gestational ages for the mothers who delivered macrosomic infants in this study were 36.2, 37.1, 38.3, and 41.1 weeks.

Langer and colleagues (1994) reported 1.4 % incidence of shoulder dystocia for their conventional group and 0.4 % for their intensified group compared to 0.5 % in their nondiabetic control group. The one incident of shoulder dystocia (5.9 %) for the DPC

participants occurred during the delivery of a 40.6 weeks' gestation fetus. The mother was of African American descent, 18 years old, and pregnant for the first time. The newborn weighed 4130 g (LGA) and was admitted to the Neonatal Intensive Care Unit for observation with no subsequent sequelae. Weight gain for this mother while on diet and insulin therapy equaled the average for the women under study. This participant's care in the DPC occurred over a 3 week period consisting of 5 visits. She performed 43 of the possible 84 (52 %) requested glucose evaluations during her DPC enrollment. Although her average fasting glucose levels were below average for this group her average postprandial lunch and dinner values were among the highest. This mother's $HgbA_{1c}$ percentage at delivery was within the normal range.

The incidence of neonatal hypoglycemia in Langer and colleagues (1994) study varied from 20.0 % for their conventional treatment group to 3.8 % for their intensified treatment group. The rate of hypoglycemia in their nondiabetic control group was 2.5 %. Hod and colleagues reported the incidence of neonatal hypoglycemia to be 2.5 - 19% for infants born to women with GDM (Hod et al., 1991).

Hypoglycemia occurred once in the infants born to woman with GDM in the study sample (5.9%). This African American mother delivered at 37.1 weeks (VBAC) a newborn weighing 4290 g (LGA). Total length of participation in the DPC for this mother was 11 weeks, 12 clinic visits. She collected 92 blood glucose values during the 4 weeks prior to delivery (82 %). Fasting blood glucose values for this client were next to the highest in the sample. Her postprandial blood glucose values consisted of the 4^{th}

highest value for breakfast, the lowest value for lunch, and the median value for dinner. Her treatment regime consisted of diet and exogenous insulin and she gained the least amount of weight of the study sample.

Limitations of the Study

The findings of this research study must be considered in light of several limiting factors. First a descriptive study is the least rigorous type of study that can be accomplished but remains a necessary step in the research process (Polit & Hungler, 1995). Inclusion of a comparison group of women with GDM who did not receive case management and delivered in the same facility could serve as a control for this study. Descriptive studies limit the type of data analyses that may be undertaken. The number of women cared for by this program since its establishment January, 1996, provided a small sampling base. Use of convenience samples also limits the generalizability of study results. Reliance on noncomputerized medical records limit the availability of information. Use of a data base composed of glucose evaluations downloaded directly from memory-based reflectance monitors would prevent human error during data transcription and ensure valuable information is not accidentally separated from medical records.

Collection of birth weight data by percentile versus actual weight is a more accurate way to compare newborns across gestational ages (Arbuckle et al, 1993). This study collected data on birth weight percentile using the Colorado "growth charts". The true value of birth weight norm use must be considered in light of the continued use of outdated guidelines such as the Colorado "growth charts" established in 1963. The need

to reestablish birth weight norms every 5-10 years is noted in the literature but not practiced by most inpatient facilities (Arbuckle et al). This same process holds true for use of BMI versus actual weight for computing maternal weight gain. This study is limited by the use of maternal weight and not maternal BMI and the failure to include exercise as a treatment method. Investigating neonatal hypocalcemia is also a limitation since the delivering facility did not collect these data.

Implications for Nursing Case Management

The major implication for nursing case management found in this study is the need to carefully document any interactions between NCMrs and clients. Secondary to the researchers personal knowledge of NCMr interaction, the lack of documented evidence of NCMr interactions was unexpected. Mullahy, (1995) addressed the need to document all types of communications between the NCMr and the client. She encouraged the use of personalized form letters in the absence of any other documented communication and highlighted the ability of these messages to reinforce important messages to the client.

A second important implication from this study for NCMrs is the need for increased maternal support and follow-up as the time of delivery draws near. Although the average number of blood glucose evaluations was greater the week prior to delivery than the 4 week period preceding delivery there was a gradual decline in the number of evaluations obtained as the week prior to delivery progressed. This trend was also noted during the intrapartum period when the maternal glycemic control most effects neonatal glycemia (Hawdon & Aynsley-Green, 1996). This decrease may be related to a

misunderstanding of the importance of euglycemia at that crucial time and or to the difficulty in obtaining blood glucose evaluations when delivery is at hand.

Recommendations for Future Nursing Research

Nursing research using Donabedian's structure-process-outcome paradigm helps determine quality prenatal care for women with GDM, care that is appropriate and necessary in order to achieve the best possible clinical outcomes (Korn, 1992). The goal of case management is to determine care that is also cost effective. Future research comparing the outcomes and costs of an interdisciplinary case management process with other processes carrying for women with GDM as a prospective study is needed. This study can serve as a pilot study laying the foundation for the type of data that is currently available in the medical record and indicating needed improvements in design and indicators studied. Use of BMI to determine appropriate maternal weight gain and updated charts to determine birth weight percentiles are indicated. Also use of a data base composed of glucose evaluations downloaded directly from memory-based reflectance monitors would prevent human error during data transcription and ensure availability of valuable data. Inclusion of exercise as a treatment modality as discussed in the review of literature is recommended (Jovanovic-Peterson & Peterson, 1991; Metzger & the Organizing Committee, 1991). Collection of data related to other neonatal complications (Hawdon & Aynsley-Green, 1996) such as hyperbilirubinemia, respiratory complications, and polycythemia versus hypocalcemia is warranted. Determination of sample sizes required for power analysis and coordination of a multisite study could ensure more generalizable results. Further research as proposed by Persily

(1996) regarding treatment adherence and anxiety scores for women with GDM in other populations could be incorporated.

Summary

The purpose of this study, to describe an interdisciplinary gestational diabetes program, was accomplished by examining the process of case management and the perinatal outcomes of program participants. This structure-process-outcome method of quality assessment was first proposed by Donabedian (1966). Assessment of the quality of care provided the program participants studied and their perinatal outcomes provided greater insight into the benefits of an interdisciplinary gestational diabetes program (Donabedian, 1982; Lang & Marek, 1992).

Findings of this study include the importance of documented evidence of interactions by each discipline to the process of interdisciplinary case management. Documented NCMr interactions in this study were limited. The reduction in the frequency of blood glucose evaluations the week prior to delivery and the limited evaluation of blood glucoses during the intrapartum period are important observations. Replication of a similar study that is prospective in nature and incorporates multisite collaboration is recommended. In order to establish case management of women with GDM using an interdisciplinary team as a method of quality health care further examination of the structure, process, and outcomes of this process must be continued.

APPENDIX A:

GDM INTERDISCIPLINARY TEAM DATA COLLECTION TOOL

Process as it relates to each research question:

1. How many visits did the patient attend in the DPC?_____

2. When did the patient begin care in the DPC? Date_____ Indicated EGA_____

   When did the patient deliver? Date_____ Indicate if EGA was corrected _____

3. The following questions are related to the time the patient was enrolled in the DPC.

   How many times did the patient see the perinatologist? _____

   How many times did the patient see the senior resident? _____

   How many times did the patient see the resident? _____

   How many times did the patient see one of the clinic RNs? _____

   How many times did the patient see the Dietitian? _____

   How many times did the patient see the Perinatal NCMr? _____

4. Was the patient referred to resources not provided by the interdisciplinary team?

   Yes No Number of times referred to include sources of referrals _____

   _____ _____

   _____ _____

   _____ _____

   _____ _____

5. If answered yes to question #4, how many times did the patient indicate the resource was sought or that the chart has documentation to that effect? _____

Outcomes:

6. What was the maternal weight gain in lbs. documented in the L&D record?

_____

7. How many blood glucose values were documented on the patient self-monitoring logs during the four weeks prior to delivery? _____

8. What were the last seven days fasting blood glucose values documented on the patient's self-monitoring logs?_____ _____ _____ _____ _____ _____

_____

9. What were last seven days postprandial blood glucose values prior to delivery documented on the patient's self-monitoring logs?

_____ _____ _____ _____ _____ _____ _____ _____

_____ _____ _____ _____ _____ _____ _____ _____

_____ _____ _____ _____ _____ _____ _____ _____

_____ _____ _____ _____

10. Were $HgbA_{1c}$ values documented for the patient? Yes No

11. If answered yes to question #10, Indicate the dates the first and last $HgbA_{1c}$ values were drawn and the lab results. Then using a metal Triphasil® pregnancy calculator confirm the latest EGA.

Date	$HgbA_{1c}$ values	Calculated EGA

12. What birth weight (grams) was documented in the newborn's record? _____

13. What length (centimeters) was documented in the newborn's record? _____

14. According to the newborn's EGA what was the birth weight percentile recorded in the newborn's record? SGA AGA LGA

15. What was the 1st neonatal glycemic value obtained? _____

16. What was the neonatal calcium value obtained? _____

17. Was there a documented incident of shoulder dystocia in the newborn record or in the maternal record? Yes No Circle the record in which it was documented.

APPENDIX B:

HUMAN SUBJECTS APPROVAL

Human Subjects Committee

THE UNIVERSITY OF
ARIZONA
HEALTH SCIENCES CENTER

1622 E. Mabel St.
P.O. Box 245137
Tucson, Arizona 85724-5137
(520) 626-6721

27 February 1997

Kathy E. Sears, Masters Candidate
c/o Ida M. Moore, Ph.D.
College of Nursing
PO BOX 210203

RE: PERINATAL OUTCOMES FOR WOMEN DIAGNOSED WITH GESTATIONAL DIABETES MELLITUS WHO PARTICIPATE IN AN INTERDISCIPLINARY GESTATIONAL DIABETES PROGRAM

Dear Ms. Sears:

We have received documents concerning your above cited project. It is our understanding that this project involves the review of existing medical records and that patient identifiers will be removed prior to data analysis. Therefore, regulations published by the U.S. Department of Health and Human Services [45 CFR Part 46.101(b) (4)] exempt this type of research from review by our Committee.

Thank you for informing us of your work. If you have any questions concerning the above, please contact this office.

Sincerely yours,

William F Denny, M.D.
Chairman
Human Subjects Committee

WFD:js
cc: Departmental/College Review Committee

19 February, 1997

To Whom It May Concern,

I was contacted concerning a retrospective medical records review by a graduate student from the College of Nursing, University of Arizona, as a data collection method for completion of her Master's Thesis. The desired records are of women and their children who delivered between 1 January 1996 and 1 March 1997. The number of records to be reviewed will be less than 75 total.

Upon ~~Pending~~ human subjects approval for this research, Kathy E. Sears, BSN, MS(C), will be granted access to the requested medical records.

Mary Anne Desanti
Medical Records Department
University ~~of Arizona~~
Medical Center

University Medical Center

CONDITIONS OF ADMISSION TO UNIVERSITY MEDICAL CENTER HOSPITAL

LOCATION DATE

PATIENT NAME

PATIENT NUMBER

INSTRUCTIONS: This is an important document. It forms a contract concerning the patient's treatment at University Medical Center (the "Hospital"). When you initial a box below, that means you have read, or have had read to you, and understand the paragraph opposite the box. Items 1-10 apply to all patients.

☐ **1. RELATIONSHIP BETWEEN THE UMC AND THE UNIVERSITY.** University Medical Center Corporation ("UMC") operates the Hospital and is a separate corporation which maintains academic and educational ties with the University of Arizona. The Hospital is the primary teaching hospital for the College of Medicine and other health related colleges of the University of Arizona. The Hospital is not operated by the University of Arizona or the Arizona Board of Regents and neither the University of Arizona nor the Arizona Board of Regents is responsible for anything UMC or its employees do or do not do. Physicians, medical students, nurses, student nurses, andany other students or health care personnel participating in educational programs at the Hospital may observe and/or participate in testing and treatment of the patient, as determined to be appropriate by the patient's doctor.

☐ **2. RELATIONSHIP BETWEEN HOSPITAL AND DOCTORS.** UMC permits surgeons, pathologists, radiologists, anesthesiologists, and other physicians, and may permit certain other practitioners who are licensed to provide independent treatment or care (all of whom are referred to generally as "Doctors") to provide medical services a the Hospital. Doctors act independently of the Hospital and are not controlled or directed by the Hospital or UMC in admitting, attending, treating, consulting or otherwise furnishing services to the patient. Doctors have responsibility for directing the care of the patient at the Hospital. DOCTORS ARE NOT EMPLOYEES OR AGENTS OF UMC. UMC is not responsible or liable for the selection of any doctor, the actions made by a doctor, or anything a doctor directs Hospital employees to do or not to do.

☐ **3. PATIENT'S CONSENT TO SERVICES BY HOSPITAL.** UMC is authorized to provide the patient with hospital services and procedures as ordered and directed by the patient's doctor. This includes examinations, tests, laboratory procedures, x-rays and other services, and may also include use of equipment, medications and other materials related to the patient's treatment and care, all of which will be charged to the patient. In exchange for the Hospital providing services to the patient, the undersigned agrees to make an advance payment or deposit if requested and to pay all of the patient's Hospital charges as and when billed, except to the extent UMC agrees otherwise in a written financial agreement. UMC may bill the patient periodically before the patient is discharged. UMC reserves the right to charge a late charge of up to 1½% per month (18% ANNUAL PERCENTAGE RATE) on all hospital charges which are not paid within thirty days of the date billed.

☐ **4. RELEASE OF INFORMATION TO PUBLIC OR MEDIA.** If asked by any person, UMC may make available to the public certain basic information including the patient's name, address, age, sex, the reason for the patient's treatment, the nature of the patient's condition and the general nature of any treatment given the patient. IF THE PATIENT OR THE PATIENT'S LEGAL REPRESENTATIVE DOES NOT WANT THIS INFORMATION TO BE RELEASED, A WRITTEN REQUEST MUST BE GIVEN TO UMC. UMC will upon request provide a separate form for this purpose.

☐ **5. OTHER RELEASE OF INFORMATION.** UMC is authorized to disclose all or any part of the patient's Hospital records including information regarding alcohol/drug abuse or HIV related information: (a) to any insurance company, health maintenance organization, preferred provider organization, employer, governmental agency or other person who is or may become responsible for the payment of the patient's Hospital charges; (b) to any physician or agency that referred the patient to the Hospital; (c) to any doctor or agency that provides the patient with continuing care services after the patient leaves the Hospital; (d) to any insurance company that provides insurance to UMC or any doctor who provides service to the patient at the Hospital, as well as their attorneys and claims agents; (e) as necessary or appropriate for medical education and research; (f) in connection with any review of the quality or appropriateness of care provided at the Hospital; (g) in collecting the patient's Hospital bill and (h) otherwise as required by law. In addition, UMC is authorized to use information contained in its business records to solicit charitable contributions to UMC.

☐ 6. PERSONAL VALUABLES/PERSONAL PROPERTY. The Hospital maintains a safe for the safekeeping of money and valuables. Items secured in the safe may be retrieved only between 6:00 a.m. and 10:00 p.m., Monday through Friday, and 6:00 a.m. and 8:00 p.m. weekends and holidays). The Hospital shall not be liable for the loss or damage to any money, jewelry, furs, documents, or other articles unless placed in the safe. For items deposited in the Hospital's safe, the limit of the Hospital's liability in case of loss or damage shall be $500.00. In addition, the Hospital shall not be liable for loss or damage to any personal property, such as bridgework, dentures, eyeglasses or clothing retained in the possession of the patient during his stay in the hospital.

☐ **7. OBTAINING INFORMATION.** The undersigned agrees to provide and UMC is irrevocably authorized to obtain such information concerning the patient and the patient's financial condition as UMC judges necessary (a) to establish that the patient is covered, qualified or eligible for benefits under any insurance policy, health maintenance organization, governmental program or from any other third party payor, (b) to establish or verify the patient's credit worthiness, or (c) to collect Hospital charges. The following sources are authorized to provide such information to and as requested by UMC: employers, banks and other financial institutions, insurance companies, governmental agencies, health maintenance organizations, physicians and all other organizations, institutions or persons. A photocopy of this authorization will be considered as effective and valid as the original.

☐ **8. LANGUAGE.** The undersigned speaks, reads and understands the ☐ English language ☐ Spanish language

☐ **9. SPECIAL MESSAGES.** I have received the special message from ☐ Medicare ☐ Champus.

☐ **10.** a. Was the patient advised that he/she has a right to receive information concerning advance directives? ☐ Yes ☐ No
b. The patient requested and was given information about advance directives? ☐ Yes ☐ No
c. Does the patient have a completed advance directive? ☐ Yes ☐ No ☐ Unknown ☐ Living Will ☐ Health Care Power Of Attorney
d. Was a copy of the advance directive given to UMC for inclusion in the medical record? ☐ Yes ☐ No
e. Did the patient recieve a "Patient Information, Rights and Responsibility" brochure? ☐ Yes ☐ No

The following applies to inpatients only.

☐ **11. DISCHARGE FOR DISRUPTIVE CONDUCT.** The patient will be subject to immediate discharge if, while in the Hospital, he or she (a) engages or threatens to engage in any criminal act, (b) verbally abuses doctors, Hospital staff or other patients or persons, or (c) refuses to consent to treatment or refuses to follow orders or directions of doctors or staff members, if the refusal may prevent a doctor or UMC from providing adequate care for the patient or any other patient at the Hospital. UMC shall not be responsible or in any way obligated to the patient if the patient is discharged for any of these reasons.

☐ **12. PATIENT OWNED APPLIANCES/RADIO TRANSMITTING DEVICES.** UMC prohibits the use of cellular phones and other radio transmitting devices in patient care areas. Patient owned appliances are generally not allowed in the Hospital. Electric shavers and hair dryers may, under some circumstances, be permitted by UMC, in its discretion, for use only in general care areas.

THE UNDERSIGNED HAS READ THE FOREGOING IN ENGLISH OR SPANISH ON THE REVERSE SIDE, OR HAS HAD THE FOREGOING READ TO HIM OR HER IN ENGLISH OR SPANISH, AS THE CASE MAY BE, HAS RECEIVED A COPY OF THIS DOCUMENT AND IS THE PATIENT OR IS DULY AUTHORIZED AS THE PATIENT'S AGENT TO EXECUTE THIS DOCUMENT AND ACCEPT ITS TERMS.

Date of Signing / Fecha en que se firma _____ Time / Hora _____

Patient / Paciente

Patient's Agent or Representative / Agento o Representante de Paciente

Witness / Testigo

Date of Signing / Fecha en que se firma _____ Time / Hora _____

Relationsh to Patient / Parentesco o Relación con el Paciente

Witness / Testigo

UMC 04-16 (REV 1/96) **UNIVERSITY MEDICAL CENTER COOPERATES WITH THE ARIZONA ORGAN BANK TO FACILITATE ORGAN AND TISSUE DONATIONS.**

MEDICAL RECORDS

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